

GLOBAL JOURNAL OF MEDICAL RESEARCH: K

Interdisciplinary

Crescendo TIAs and Headache

Magnitude of Late ANC Booking

Highlights

Spontaneous Vertebral Artery

Primary Paraovarian Adenocarcinoma

Discovering Thoughts, Inventing Future

VOLUME 19 ISSUE 1 VERSION 1.0



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Spontaneous Vertebral Artery Dissection Presenting with Crescendo TIAs and Headache

By Dr. Nosakhare I Idehen & Dr. Mohammed Awad

Summary- We present the case of a man in his thirties who had attended the emergency department with complaint of a distressing headache and associated intermittent facial droop with occasional slurred speech. The patient's symptoms were bizarre in their nature as they were random, not sustained and he had long intervals when he was asymptomatic and was his normal self. During the course of admission his symptoms evolved resulting in neurological deficits which were more sustained, prompting the need for further imaging beyond the initial plain CT brain which showed no abnormality.

This led to the diagnosis of vertebral artery dissection (VAD) complicated with an ischaemic stroke in the posterior inferior cerebellar artery distribution (PICA) on MRI/MRA. Dual anti-platelet treatment was commenced with the patient attaining gradual symptomatic improvement prior to discharge. He has reported some degree of neurological sequelae which he described as intermittent poor coordination on follow up visit in clinic after discharge.

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Spontaneous Vertebral Artery Dissection Presenting with Crescendo TIAs and Headache

Dr. Nosakhare I Idehen ^a & Dr. Mohammed Awad ^a

Summary We present the case of a man in his thirties who had attended the emergency department with complaint of a distressing headache and associated intermittent facial droop with occasional slurred speech. The patient's symptoms were bizarre in their nature as they were random, not sustained and he had long intervals when he was asymptomatic and was his normal self. During the course of admission his symptoms evolved resulting in neurological deficits which were more sustained, prompting the need for further imaging beyond the initial plain CT brain which showed no abnormality.

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I. BACKGROUND

Spontaneous vertebral artery dissection has an estimated incidence of 1-1.5 per 100,000 classing it as a rare condition.^[1] The wide symptom spectrum that mimics other seemingly more common pathologies can mean it is easily missed or leads to wrong diagnosis.

As a major cause of stroke in young adults with patients presenting at times with symptoms that may not manifest as full blown neurological deficit in the first instance, we have considered it important to report on this case to increase awareness on this pathology and improve understanding on how patients may present and lay emphasis on the need to consider vertebral artery dissection in the differentials for relevant patients, cause prompt diagnosis and early treatment is important for good prognosis and recovery. Making a diagnosis of vertebral artery dissection can prove to be difficult as the presenting symptoms overlap with other pathologies. It can be challenging to convince overworked, under resourced radiologists of the importance of conducting an urgent MRI. With greater familiarity of the possible clinical features this could be eased.

There has been an increase in recent decades in the number of cases reported and the accessibility to

better diagnostic imaging modalities has been attributed as one of the factors rather than an actual rise in incidence.^[2] With clinicians having higher index of suspicion and utilising this improved diagnostic techniques these numbers may well continue to rise.

With absence of risk factors and atypical presentation, diagnosing VAD and posterior circulation events in an acute setting can be challenging as it heavily reliant on imaging services, thus admitting patients who have symptoms suggestive of VAD for further imaging in normal hours if the resources for urgent imaging are unavailable, would be a better outcome and improve patient experience than dismissing them just because they don't fit any clear clinical pattern.

II. CASE PRESENTATION

A 36-years old gentleman self-presented to the emergency department with complaints of sudden onset, intermittent, severe headache, shooting right sided facial pain with associated right sided weakness, slurred speech, dizziness and leaning to the right side when walking. The patient also described mild neck stiffness, mild photophobia, and jaw claudication. There was no history of trauma nor past medical history of concern.

The characteristic of note was the sporadic nature of this symptoms as they seemed to occur only when patient was being assessed, with well-spaced symptom free intervals. His vital signs recorded were all within the reference limits. Clinical examination in the emergency department did not yield any useful information as his symptoms were not reproducible besides his intermittent calling out in pain, this was not convincing for emergent imaging and on account of patient's distress and poorly controlled symptoms he was referred to the medical team for review and further management. He was admitted under the neurology team and on assessment the following day symptoms had evolved and there was demonstrable neurological deficit.

On examination there was altered sensation in the distribution of the 5th cranial nerve on the right side of the face, dysmetria and dysdiadochokinesia in the right upper limb. There was also some impairment of coordination of the right lower limb. There were no power, tone or reflex deficits observed. His headaches had resolved to burning episodic facial pain by this time.

^aAuthor ^a: Specialty Registrar, Department of Emergency Medicine, Lancashire Teaching Hospital, UK.

e-mail: idehen.nosakhare@lthtr.nhs.uk

^aAuthor ^a: Junior Clinical Fellow, Department of Emergency Medicine, Lancashire Teaching Hospital, UK.



This was approximately 32 hours from initial presentation with earlier symptoms which in retrospect were caused by the dissecting vertebral artery and transient ischemic attacks involving the inferior cerebellar peduncle including parts of the area of supply of the right posterior inferior cerebellar artery (PICA).

III. INVESTIGATIONS

CT-brain done on the day of admission showed no abnormalities and MRI with contrast conducted the MRI/MRA Images shown below:

following day showed right vertebral artery dissection with small infarct involving the right inferior cerebellar peduncle and part of the cervicomedullary junction which suggested involvement of part of the right posterior inferior cerebellar artery.

Other routine investigations conducted include FBC, U & E, Coagulation profile, ESR and CRP were also all within reference limits as well as a normal ECG tracing.

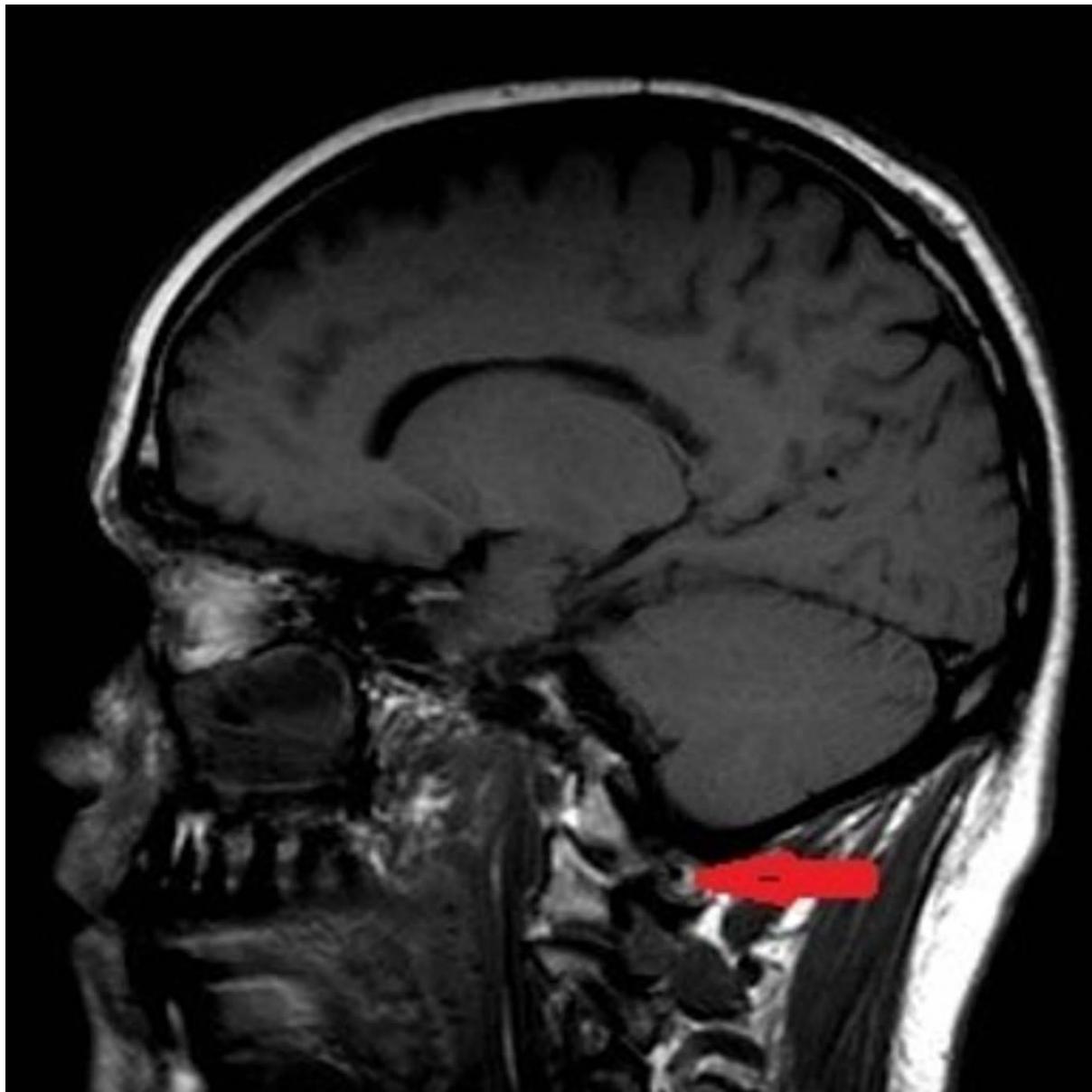


Fig. 1: Parasagittal T1 weighted image showing semi-lunar hyperintense clot within the false lumen in the right vertebral artery as it courses above the C1 neural arch.

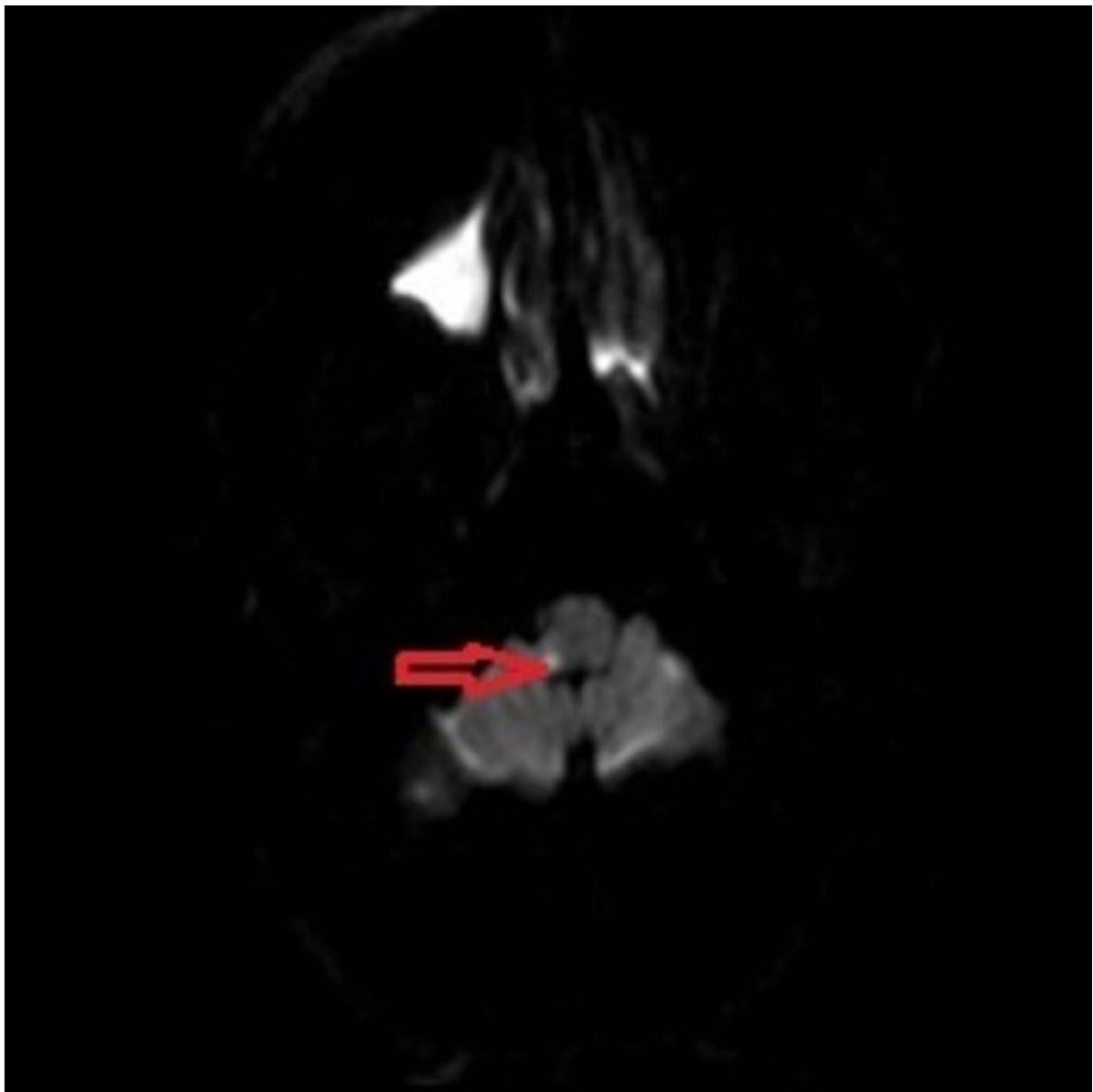


Fig. 2: Diffusion weighted image showing an acute infarct involving the inferior cerebellar peduncle in part of the right PICA distribution.





Fig. 3: T2 weighted images showing loss of right vertebral artery flow void.

IV. DIFFERENTIAL DIAGNOSIS

The non specific and sporadic nature of the symptoms gave rise to a broad list of differentials listed below:

Trigeminal neuralgia

Migraines

Internal carotid artery dissection

Sub-arachnoid haemorrhage

Cluster headaches

Focal seizure disorder (patient appeared to have myoclonic jerks on some occasions)

Conversion disorder

V. TREATMENT

With diagnosis now confirmed as vertebral artery dissection complicated with a stroke patient was commenced on Aspirin and Clopidogrel with Dalteparin included only during admission period. He was treated with regular analgesia for pain control.

There was progressive improvement of symptoms with treatment. After review by the physiotherapy team on the 8th day of admission he was discharged home to continue with dual anti-platelets and planned reviews in the outpatient clinic

VI. OUTCOME AND FOLLOW-UP

On review at the follow up cerebrovascular clinic after discharge he reported resolution of symptoms to a large extent and described mild unsteadiness on his right side, this is said to occur intermittently.

VII. DISCUSSION

Vertebral artery dissection (VAD) is one of the most common causes of stroke in young people. It is broadly classified under cervical artery dissections which include Internal carotid artery dissection (ICAD) and Vertebral artery dissection. ICAD occurs 5 times more frequently than VAD and together they account for 20% of stroke in the young.^[3]

The pathophysiology of VAD is not well understood, multiple factors are postulated to contribute to its occurrence which include environmental risk factors (cervical trauma, recent infection, sudden movement of the head, and migraine) and protective factors (hypercholesterolemia, overweight) have been described.^[4]

Genetic predisposition has also been documented to be an intrinsic factor in the development of a VAD.^[2] Other contributory factors mentioned in case reports on VAD include high blood pressure surges^[5] and neck manipulation.^[6] However fewer cases were deemed to be spontaneous^[7,8] with some authors suggesting there may have been minor or trivial injury around the neck preceding spontaneous cases.

The diagnosis of traumatic vertebral artery dissection is reserved for those with significant trauma including road traffic accidents or penetrating neck injuries.

The dissection could be intracranial or could be located outside the cranial vault. Despite their similarity in size the extracranial portion of the vertebral artery is more prone to dissection than the intracranial portion.^[9]

Dissection occurs when blood accumulates in the wall of the blood vessel. A tear in the tunica intima (the inner layer), allows blood to enter the tunica media.

The reduced rate in blood flow and endothelial injury encourages thrombus formation, with the inevitable emboli causing brain stem and cerebellar infarctions, as was the case with the patient in this report. Dissections involving the tunica adventitia could form a pseudo aneurysm, which can rupture causing a sub-arachnoid haemorrhage.^[3]

Headache, vertigo, vomiting and unilateral extremity weakness are well recognized presentations of VAD and cerebrovascular accidents.^[10,11]

The clinical versatility of this pathology includes symptoms which besides headache and neck pain (most common symptoms) could include postural imbalance, facial numbness, dysphagia, dysphonia, unilateral facial paraesthesia as well as unilateral deafness.^[12] Since headache and the above listed

symptoms could precede ischemic symptoms to the brain by minutes or days, these red flags could be considered as warning signs to provide a chance for diagnosis before ischemia sets in. Putting these into account patients who present with unexplained or unusual neurological symptoms that could be suspicious for vertebral artery dissection would benefit from detailed and thorough neurological examination as well as appropriate imaging studies.

Current evidence shows no change in incidence but rather more accurate diagnosis with the advancement in imaging techniques and increased availability of the study modalities required in reaching a conclusion.^[2]

A review of the literature from 2008 till 2018 shows 44 documented cases on MEDLINE (with 5 cases from the UK) of various presentations of vertebral artery dissection and in not a few of the cases diagnosis was reached when these patients were admitted for other reasons, as VAD was not considered a likely priority for investigation on the list of differentials and it was not uncommon for the patients to develop further neurological deficits while on admission, which prompted more detailed imaging studies.

The American Heart Association (AHA), American Stroke Association (ASA), and the International Headache Society all recommend MRI/MRA with fat suppression as the best initial screening test.^[13,14] However, they also indicate that CTA and angiography scans can be obtained, especially if there is doubt in the diagnosis or the dissection is very early.^[13,14]

Management is targeted towards preventing stroke and also improving neurological outcomes. Most dissections will heal spontaneously, but each patient should receive treatment to prevent the possible thromboembolic and hemodynamic complications of dissection. This typically includes anticoagulation or antiplatelet agents, but some patients may require endovascular or surgical therapy.^[15] There is no known superiority between antiplatelet or anticoagulant therapy, so either of both can be safely given to patients.

Prognosis is excellent with overall good functional recovery and low rates of recurrence of bleeding, dissection or ischemia.

VIII. LEARNING POINTS

- Consider spontaneous vertebral artery dissection in a patient presenting with unexplained craniocervical pain or headache and no other neurological deficit.
- Vertebral artery dissection is an important cause of stroke in the young.
- Vertebral artery dissections can present with TIA affecting the cerebellar circulation.
- Overall the prognosis is good for patients with VAD, but recurrent stroke, recurrent dissection and even





death could occur in some patients, so a high index of suspicion should remain for relevant patients.

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Rare Primary Paraovarian Adenocarcinoma in Postmenopausal Woman: Case Report and Review

By Dr. Anjani Dixit & Dr. Shanti Jayaseelan

Abstract- Malignant paratubal cancers have extremely rare occurrence and have not been sufficiently described and discussed in literature. We describe case of an 80 years old gravida 5 para 4 postmenopausal woman presented with pain in lower abdomen and spotting per vagina. USG followed by MRI showed large mid pelvic right adnexal complex predominantly cystic lesion of 8.7x7.1x5.9 cm size with small exophytic solid component (3.1x2.8x2.6 cm). Postoperatively it was diagnosed as a case of high grade paratubal adenocarcinoma (stage T1N0M0). The patient received 3 cycles of adjuvant chemotherapy with carboplatin and docetaxel. Patient has had no recurrence till date (20 months post treatment).

Keywords: *paratubal adenocarcinoma, adnexal complex, primary tumour, broad ligament.*

GJMR-K Classification: NLMC Code: WP 460



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Dr. Anjani Dixit ^a & Dr. Shanti Jayaseelan ^a

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Keywords: *paratubal adenocarcinoma, adnexal complex, primary tumour, broad ligament.*

Key Messages: Primary paratubal adenocarcinoma is an extremely rare case. To the best of our knowledge, we here report the oldest patient (80 years) with this condition. She presented with vaginal spotting which is a close mimic of endometrial cancer in this age. Diagnosis and management together with review of literature are discussed. It is observed that due to rarity of the case, there is no consensus on management. Further studies and reporting are recommended.

I. INTRODUCTION

Primary paraovarian malignancy is an extremely rare condition, so much so that very little is known about their epidemiology, biological behaviour, prognosis, protocols for diagnosis and management. The incidence of paraovarian malignancy is also not known¹⁶. Very few cases have been reported in literature till date. We hereby present, to the best of our knowledge, the oldest patient in literature with paraovarian malignancy. Diagnosis and management together with review of literature are discussed.

II. CASE REPORT

An eighty years old gravida 5 para 4 postmenopausal woman presented with continuous

Author ^a: MBBS, DNB, Senior Resident, Department of Obstetrics & Gynaecology, Holy Family Hospital, 143A, First floor, Shahpurjat, New Delhi-110049. e-mail: doc.anjani@gmail.com

Author ^a: MBBS, MD, Senior Consultant, Department of Obstetrics & Gynaecology, Holy Family Hospital, Okhla road, New Delhi- 110049. e-mail: shanthijayaseelan@gmail.com

pain in lower abdomen for last one and a half year and vaginal spotting for last 4 days. Patient was menopausal for last 30 years. On pelvic examination, cervix and vagina were assessed to be normal, uterus was normal and anteverted, a cystic mass of approximately 6x6 cm in size was felt close to uterus, and POD was free. USG was suggestive of thin walled anechoic cystic mass on right side, 8x6x6 cm with few internal septae. MRI pelvis showed large midpelvic right adnexal complex predominantly cystic lesion of size 8.7 x 7.1 x5.9 cm with small exophytic solid component (3.1x2.8x2.6 cm). The exophytic solid component was focally indenting anterior rectal wall with no apparent infiltration. Endometrial thickness was 1.7 mm, smooth regular margins and fluid – fluid levels were seen. Endometrial curettage was done and histopathology report showed senile endometrium. Her serum CA125 level was normal.

Patient underwent exploratory laparotomy. No ascites or peritoneal implants were seen. Peritoneal wash was sent for cytological examination. Both the ovaries, fallopian tubes and the uterus were normal in appearance. A large paraovarian cystic mass measuring 8x6x4cm was seen on right side with right fallopian tube stretched over it. TAH with BSO with cystectomy was done. Full biochemical and radiological examinations showed no evidence of metastasis or any other disease process. We staged the primary paraovarian tumour as T1aNOM0. Five weeks later, patient underwent 3 cycles of adjuvant chemotherapy with carboplatin and docetaxel. Patient is doing well in follow up visits till date (20 months post treatment).

III. PATHOLOGY

On postsurgical examination, peritoneal fluid cytology showed no evidence of malignancy. On macroscopic examination, paraovarian cyst was found to be uniloculated, filled with thin hemorrhagic fluid and a firm, greyish white nodule measuring 3x2.5x2 cm was seen in the wall of the cyst, which on cut surface was grey white, granular with large areas of necrosis. Rest of the cyst wall had smooth inner surface with foci of hemorrhages. No tumour was found in the bilateral ovaries and fallopian tubes.

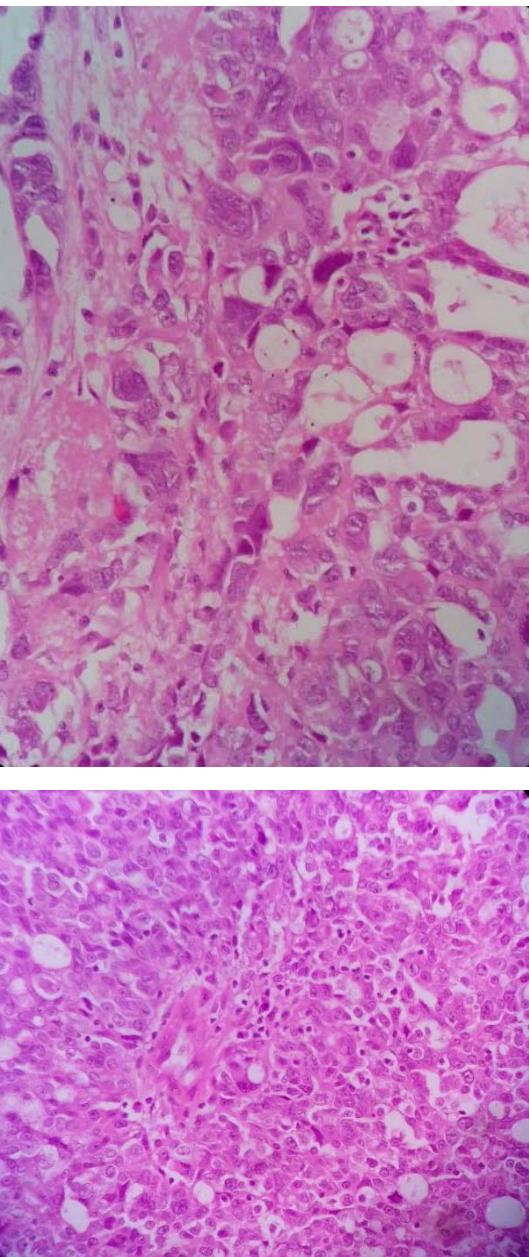


Fig. 1 and Fig. 2: High grade serous adenocarcinoma showing papillary structure with marked pleomorphism and frequent mitosis

Microscopic examination of the right adnexal mass revealed malignant tumour with solid and tubulocystic pattern with cells lining the tubules having hobnail appearance. There was marked pleomorphism in the neoplastic cells in the solid area suggestive of high grade serous adenocarcinoma from paraovarian cyst (Fig. 1 and 2). Large areas of necrosis and stromal lymphocytic infiltration were seen. Sections of the cyst wall showed columnar to cuboidal to flattened cell lining with underlying fibrosis and infiltration by hemosiderin laden macrophages. There was no lymphovascular space invasion. Endomyometrium showed senile cystic atrophy with atrophic myometrium. Bilateral fallopian tubes and ovaries were unremarkable.

IV. DISCUSSION

Secondary tumours in broad ligament are not uncommon but primary tumours are rare. Commonly seen primary tumours are leiomyomata, serous and papillary cystadenoma of borderline malignancy but primary malignant tumours are very rare⁹. Primary broad ligament carcinoma as mesonephroma was first reported by Schiller in 1939¹.

In our case primary tumour was located in or on the broad ligament and completely separated from ipsilateral ovary, fallopian tube, and uterus. This satisfies the criteria given by Gardner *et al* in 1957 to diagnose primary carcinoma of broad ligament origin⁴.

The age range in reported cases of broad ligament malignant tumours is 13 to 80 years (median 43 years) and the age range of borderline tumours is 28-38 years (mean 32.6 years) with 43.4% below the age of 40 years. To the best of our knowledge, ours (80 years) is the oldest case reported in the literature. In contrast, mean age of ovarian cancer is 63 years, being rare in women below 40 years¹⁸ and mean age of borderline ovarian tumours is 10 years lower¹⁹.

Five were clear cell carcinoma (20.8%), two were papillary adenocarcinoma (8.3%), four were endometrioid (16.6%), five including ours were serous adenocarcinoma (20.8%), one was mucinous carcinoma (4.1%), and one was well differentiated adenocarcinoma (4.1%) and five were borderline serous cystadenoma (20.8%) (*Table 1*).

Most common presenting symptoms reported are lower abdominal pain and pelvic discomfort¹⁵ like in our case. Moreover, our patient also presented with vaginal spotting. Although most common cause for vaginal spotting in post-menopausal age group is senile endometritis²⁰, there is a possibility of associated endometrial carcinoma as mentioned by Aslani *et al*⁶. Hence it is important to rule out endometrial cancer in scenarios of vaginal spotting for postmenopausal women. In our case endometrial cancer was ruled out by endometrial curettage. It is to be noted that presentation of broad ligament tumour can be an incidental finding as well⁹. There is a 1.4 % to 3.8% chance of synchronous tumour of ovary and endometrium²⁰ but similar data about broad ligament tumour is not known due to rarity of cases. All the reported cases of broad ligament tumour (*Table 1*) including borderline variety were unilateral, in contrast to ovarian tumour which are 25% bilateral²¹.

For fourteen cases (58%) including ours, patients were diagnosed in stage 1 of broad ligament tumour. Two cases (8.3%) were diagnosed in stage 2, while three cases (12.5%) were diagnosed in stage 3. Staging was not known for the remaining five cases (20.8%). It is to be noted that majority of the cases, including our case, were diagnosed in stage 1. Possible

reason for the same is that tumours are encapsulated between the sheets of broad ligament. Thus rupture as well as aggressive progression is prevented due to lack of vasculature²².

Management of broad ligament tumour is often done in a similar way as that of ovarian cancer because of similarities in histology and histogenesis, i.e. commonality in coelomic epithelium¹⁰. Post-surgical adjuvant treatment is not established as the standard

procedure due to lack of evidence. It is recommended to use same principles as followed in the management of ovarian cancer¹⁵. Of the 24 cases, surgery was the singular mode of treatment in eleven cases (46%), surgery followed by chemotherapy in eight cases including our case (33%), surgery followed by radiotherapy in four cases (17%) while only radiotherapy was used in one case (4%).

Table 1: Summarised review of literature

S. No.	Author (year)	Age (years)	Size (cm)	Pathological diagnosis	Treatment	Follow up	stage
1	Schiller ¹ (1939)	43	Child's head	Clear cell	TAH+BSO, Radiotherapy	Live, 24 months	1
2	Lennox ² (1952)	45	7x6.5x6	Papillary adenocarcinoma	TAH+BSO, Radiotherapy	Live, 10 months	1
3	Telium ³ (1954)	62	Fist size	Clear cell	Enucleation	Not known	2
4	Telium ³ (1954)	32	10x8x8	Clear cell	Enucleation	Not known	1
5	Gardner ⁴ (1957)	50	-	Well differentiated adenocarcinoma	Radiotherapy	Live, 27 months	--
6	Merri ⁵ (1959)	70	13	Papillary adenocarcinoma	TAH+BSO, Radiotherapy	Live, 12 months	2
7	Czernobilsky ⁶ (1972)	29	5x4x4	LMP Serous	TAH+BSO	Not known	1
8	Genadry ⁷ (1977)	13	9x6	Serous adenocarcinoma	Adnexectomy	Live, 60 months	--
9	Genadry ⁷ (1977)	38	9x6	LMP Serous	Adnexectomy	Live, 60 months	--
10	Genadry ⁷ (1977)	36	9x6	LMP Serous	Adnexectomy	Live, 60 months	--
11	Genadry ⁷ (1977)	28	9x6	LMP Serous	Adnexectomy	Not known	--
12	Clark ⁸ (1979)	29	8x7x2	Mucinous adenocarcinoma	TAH+BSO+ omentectomy	Not known	1
13	Aslani ⁹ (1989)	51	10x6x6	Clear cell	Excision+BSO+ omentectomy, Radiotherapy	Live, 7 months	1
14	Aslani ⁹ (1989)	29	6x6x5	Endometroid	Excision+TAH+BSO, inguinal and paraaortic lymph node sampling, Chemotherapy	Live, 18 months	1
15	Aslani ⁹ (1989)	69	11x8	Endometroid	Excision of tumor + TAH+BSO, Chemotherapy	Live, 12 months	1
16	Aslani ⁹ (1989)	34	4.5x4x3.5	Endometroid	TAH+BSO+ pelvic and paraaortic lymph node dissection+ omentectomy, Chemotherapy	Live, 6 months	1
17	Altaras ¹¹ (1990)	76	12x9x8	Serous	TAH+BSO	Live, 53 months	1

18	<i>Itani</i> ¹¹ (2001)	54	4.7x5.7	Serous	TAH+BSO+ pelvic and periaortic lymphadenectomy+ omentectomy, chemotherapy	Live, 18 months	1
19	<i>Vaysse</i> ¹² (2009)	44	16x14x5	Endometroid	TAH+BSO+ Pelvic and paraaortic lymphadenectomy+ omentectomy	Live, 36 months	1
20	<i>Kaur</i> ¹³ (2011)	37	13x8x5	Endometroid	TAH+BSO+ omentectomy+ pelvic lymphadenectomy, chemotherapy	Live, 3 months	3
21	<i>Jong-Hyun Kim</i> ¹⁴ (2013)	32	17x12x10	Serous LMP	RSO+ omentectomy+ appendectomy+ peritoneal biopsies +right pelvic lymphadenectomy	Live, 24 months	1
22	<i>Miyoshi</i> ¹⁵ (2015)	71	7.4x6.4x5.2	Serous	Modified radical hysterectomy+BSO + omentectomy, chemotherapy	Live, 5 months	3
23	<i>Miyoshi</i> ¹⁵ (2015)	43	4x3.7x3.9	Clear cell	Modified radical hysterectomy+BSO + omentectomy + pelvic lymphadenectomy, chemotherapy	Live, 3 months	3
24	Our Case (2018)	80	8x6x4	serous	TAH+BSO, Chemotherapy	Live, 24 months	1

Abbreviations: TAH- Total abdominal hysterectomy, BSO- Bilateral salpingoophorectomy, RSO- Right salpingoophorectomy,

V. CONCLUSION

Survival rates and prognostic factors are inconclusive due to rarity of the tumour, lack of uniformity in treatment modalities and improper reporting. Similar to cases of ovarian cancer, follow up is important to look for relapse or any residual disease left after adjuvant therapy.

We recommend that such rare cases be reported in literature so that consensus on diagnosis and management can be evolved and established.

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Magnitude of Late ANC Booking and its Determinant Factors among Pregnant Women Attended Public Health Centers and Private Clinic in Artumafursi District, Amhara Regional State, Special Zone of Oromia, Ethiopia 2017

By Ayana Chimdessa, Nathan Estifanos & Jote Markos

Wollega University

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In Ethiopia only 34 % of women received antenatal care service at least once for their last birth. Only 11% of women had taken their first antenatal care (ANC) visit before the second trimester.

Methods: Institutional based cross sectional survey was conducted from May 1-30, 2017. All pregnant women who had attended to two public health centers and one private clinic for ANC follow up were recruited by simple random sampling method. Particularly, lottery method was used to recruit participants in to the study. Data were collected using pre-tested interviewer administered questionnaire. Logistic regression was used to analyze the data by using IBM SPSS statics version 20.0.

Keywords: *magnitude, antenatal care, determinant factors, pregnant women, ethiopia.*

GJMR-K Classification: NLMC Code: WA 108



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Ayana Chimdessa ^a, Nathan Estifanos ^a & Jote Markos ^b

Abstract- Background: Pregnancy period is the most crucial time to determine the healthy life of a woman and whole families. It is a vital period to promote healthy behaviors and parenting skills.

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Results: The study has explored the magnitude and determinant factors of late ANC booking of participants in the district. Magnitude of late ANC booking among the study participants' was massive. The overall prevalence of late ANC booking time was 252 (60.9%). Having diploma and above educational status (AOR 1.50, (95 % CI, 2.10, 1.51)), being employed (AOR 2.20, (95% CI, 2.73-1.01)) previous history of abortion (AOR 1.56 (95% CI, 2.09-1.73) and urban resident (AOR 2.10 (95% CI, 3.25-1.87)) were identified as major contributing factors for early initiation of ANC booking. Whereas, unintended pregnancy (AOR 0.45 (95% CI, 0.34, 0.21)) and having poor knowledge of ANC services (AOR 0.51 (95% CI, 0.71-0.21)) were contribute for late ANC booking.

Conclusions: The overall prevalence of late ANC booking time was 252 (60.9%). Higher educational background, being employed, previous history of abortion and urban residents were identified as major contributing factors for seeking behavior of early ANC booking. Unintended pregnancy and

having poor knowledge of ANC services negatively affect early ANC booking.

Hence, establishment of pregnant mothers' group discussion forum about ANC, creating and using Health Development Army (HAD) "for the community by the community" must be considered.

Keywords: magnitude, antenatal care, determinant factors, pregnant women, ethiopia.

I. BACK GROUND

Pregnancy period is the most crucial time to determine the healthy life of a woman and whole families. It is a vital period to promote healthy behaviors and parenting skills [1]. Utilization of health services are complex behavioral phenomenon. Empirical studies of preventive and curative services found that the use of antenatal care (ANC) services are directly related to availability, accessibility, quality, cost of services, social structure, health beliefs and personal characteristics of clients [1,3]. Antenatal care refers to education, counseling, screening and treatment throughout pregnancy period. Promoting the well-being and monitoring the health status of families is another activities need attention during the period of pregnancy [1, 2].

Attaining to world health organization (WHO) recommendations on the new model of ANC goal-oriented implementation in developing countries is mandatory. Within this new strategy, WHO recommends four antenatal care visits for low risk pregnancies and prescribes evidence-based practices for every visit and classify them in to basic components and special care of ANC depending on their previous obstetric history. World health organization recommends that all pregnant women should receive prenatal care at early stage of their pregnancy to prevent any pregnancy related complications [1,3]. In addition to this, pregnant women should be screened for HIV and syphilis infections for the sake of reducing mother-to-child transmission [2,3].

Author a: School of Nursing and Midwifery, College of Health Sciences, Wollega University, P.O Box: 395, Nekemte, Ethiopia.

e-mail: ayanayoom@gmail.com

Author a: College of Medicine and Health Science, Wollo University, Desse, Ethiopia. e-mail: estifanos9090@gmail.com

Author p: College of Health Science, Wollega University, Nekemt, Ethiopia. e-mail: amsalec2002@yahoo.com



Different studies pointed that a timely initiation of ANC has variety of benefits creating strong relationship among families, provision of individualized health promotion information, early problem identification, examination and management of maternal conditions that may later become life-threatening conditions. This time is also ideal to prepare mothers to plan for birth and care of a newborn. Those women who failed to initiate ANC at early stage may encounter negative impact of pregnancy related health conditions and may face long life health problems [1, 2, 4].

Even though pregnancy related mortality is almost always preventable, yet worldwide, more than half a million women die annually. Studies shows that about 1,600 women die every day due to pregnancy related complications. Out of these about 90-95% is accounted by sub-Saharan countries [5].

Maternal mortality is one of the major challenges that developing countries are facing today. Even though indisputable actions have been taken to reduce maternal mortality, it is still significantly high in developing world. Recent studies showed that in average 1:16 life risk mothers die of pregnancy and childbirth related problems in developing countries compared with that of developed countries which is 1:2800. Out of 520,000 estimated deaths each year, about 99% of these occur in developing world. About 300 million women in developing countries suffer from long term complications related to pregnancy and childbirth [1,5]

Despite of charge free ANC services in public health institutions of Ethiopia, there is a very low magnitude of on time ANC visit and service provision as well. The 2014 Ethiopian demographic health survey (EDHS) report indicated that about four out of every ten Ethiopian women (43%) had not received any antenatal care service for their last birth within the last five years prior to the survey [4]. In Ethiopia the prevalence of maternal and infant mortality and morbidity are amongst the highest in the world. Thus, there are 676 maternal deaths for every 100,000 live births and infant mortality rate is 59 per 1,000 live births [4]. Different studies reported that women who had never received ANC service may face lifelong health problems and even death. Despite the progress in antenatal care coverage, many countries of sub-Saharan Africa and South/Southeast Asia have unsatisfactory results of registries for WHO recommended Focused Ante-Natal Care (FANC) visits. Additionally, in sub-Saharan Africa women tends to start their first antenatal care visit either in the second or third trimester [1, 3].

According to EDHS 2014, only 34% of women received antenatal care service at least once for their last birth. Only 11% of women had taken their first ANC visit before the second trimester of their last pregnancy [4]. Therefore, it was the purpose of this study to

investigate the magnitude of ANC service coverage and factors associated with late attendance to ANC services in ArtumaFursi district, Ethiopia. The results of this study provide direction for designing targeted ANC service intervention and timely initiation of reproductive age women for ANC follow up.

II. METHODS AND MATERIALS

Institutional based cross sectional survey was conducted from May 1-30, 2017. All pregnant women who had attended to two public health centers and one private clinic for ANC follow up were recruited by simple random sampling method. Particularly, lottery method was used to recruit participants in to the study. All Pregnant women who had attended ANC service were included. Pregnant women who were critical ill during data collection period were excluded from the study. Sample size was calculated by using $p=50\%$ to obtain maximum sample size, $CI\ 95\%$, margin of error $d=0.05$ and summation of 10% considerable non-response rate. Totally, 424 participants had taken part in the study. Late booked mothers for ANC services were considered as an outcome variable for this study. Initial time of visit for ANC service was tested with independent variables. Late ANC booked mothers referred to those who had booked for the service after 12 weeks of their gestational age.

Partially adopted structured interview-based questionnaire was used for data collection. The questionnaire was prepared in English and then translated to local language (Afan Oromo) by formal translator and re-translated to English in order to check for its consistency. Finally, the local language version was used for data collection. Before actual data collection, the questionnaire was pre-tested on 5% of the sample size at Kombolcha health center. Based on the pre-test results, some amendments were done. Data was collected by 6 B.Sc. Nurses, Midwives and two trained supervisors. All data collectors and supervisors had given two days of intensive training on the objectives, procedures and content of the study.

The collected data was entered in to Epi Info 7 and exported to IBM SPSS statics version 20.0 to clean and analyze data. Frequencies, proportions, mean and summary statics were used to describe parameters under investigations. Association between outcome variable and independent variables were assessed and presented using odd ratio and confidence intervals. Multivariate logistic regression is done to control for possible confounders.

Ethical clearance was obtained from Wollo University Institutional Review Board (IRB) and given to all responsible bodies abiding with a formal letter. Written informed consent was obtained from each study participants. Participation in the study was voluntary and collected information has been kept confidential.

III. RESULTS

A total of 424 participants were involved in the study. Data from 414 (97.7%) were included in the analysis. Information from ten respondents was excluded from analysis for their incompleteness.

a) Socio-demographic characteristics

As indicated in Table 1, the mean age of respondents was 23.43 ranging from 18-49 years old.

Table 1: Socio-demographic characteristics of study participants in ArtumaFursi district, Ethiopia, 2017 (n=414)

Variable	N (%)
Age (mean = 23.43)	
18-30	262 (63.5)
31-40	87 (21.0)
41-49	65 (15.5)
Ethnicity	
Oromo	403 (97.3)
Amhara	8 (1.9)
Afar	3 (0.7)
Religion	
Muslim	248 (59.9)
Orthodox	160 (38.6)
Protestant	6 (1.4)
Occupation	
House wife	254 (61.4)
Employed	160 (38.6)
Educational status	
Never been to school	149 (36.0)
Primary	87 (12.8)
Secondary	80 (19.3)
Diploma and above	98 (11.4)
Marital status	
Married	264 (63.8)
Single	124 (30.0)
Divorced	26 (6.3)
Monthly house hold income	
<400 ETB	167 (40.3)
400 – 1,000 ETB	111 (26.8)
>1,000 ETB	136 (32.9)

b) Determinant factors for late ANC booking of pregnant mothers

Late ANC booking among the study participants was massive. The overall prevalence of late ANC booking was 252 (60.9%). Of the total, 182 (69.5%) and 31 (47.7 %) had booked late for ANC services with respective age ranges between 18-30 and 41-49 years.

Of the total, 403 (97.3%) of participants were from Oromo ethnic group. Majority 248 (59.9%) and 160 (38.6%) of respondents were Muslim and Christian followers respectively. About 264 (63.8%) of respondents were married. More than half 254 (61.4%) of participants were housewives. About 149 (36%) had never been to school and 265 (64 %) of participants were living in the rural parts of the district.



Majority 198 (74.7%) of rural residents had booked late for ANC services. The average house hold income and employment status of study participants were major factors influencing ANC booking time. About 142 (85%) of participants who were earning less than 400 Ethiopian birr per month and housewives 241 (94.9%) had booked late for ANC follow up.

c) *Obstetric history of study participants*

Obstetric history of pregnant mothers was another factor affecting ANC booking time either positively or negatively. Out of 143 (34.5 %) uniparous, about 84 (71.8%) of them had booked late for the services.

About 161(38.9%) participants had previous history of abortion. Of these, 119 (73.9%) booked early for ANC services. About 97 (24.4%) participants had unintended pregnancy; of which 86 (88.7%) were lately booked for antenatal care.

Table 2: Determinant factors for late ANC booking of pregnant mothers in ArtumaFursi district, Ethiopia, 2017 (n = 414)

Variable	Late booking for ANC follow up		
	Yes: n (%)	No: n (%)	Total: n (%)
Age (mean = 23.43)			
18-30	182 (69.5%)	80 (30.5%)	262 (63.3)
31-40	39 (44.8 %)	48 (55.2 %)	87 (21.0)
Greater than 41	31 (47.7 %)	34 (52.3 %)	65 (15.7)
Residence			
Rural	198 (74.7 %)	67 (25.3 %)	265 (64.0)
Urban	54 (36.2 %)	95 (63.8 %)	149 (36.0)
Marital status			
Married	130 (49.2 %)	134 (50.8 %)	264 (63.8)
Unmarried (get pregnancy informally)	103 (83.1 %)	21 (16.9 %)	124 (30.0)
Divorced, separate or widowed	19 (73.1 %)	7 (26.9 %)	26 (6.3)
Monthly income			
<400 ETB	142 (85 %)	25 (15 %)	167 (40.3)
400 – 1,000 ETB	90 (81.1 %)	21 (18.9 %)	111(26.8)
>1,000 ETB	20 (14.7%)	116 (85.3 %)	136 (32.9)
Occupation			
Employed	11(6.9 %)	149 (93.1 %)	160 (36.6)
House wife	241 (94.9 %)	13 (5.1%)	254 (61.4)
Educational status			
Never been to school	137(92%)	12(8%)	149 (36.0)
Complete primary	66(75.9%)	21(24.1%)	87 (21.0)
Secondary complete	59 (73.8%)	21 (26.2%)	80 (19.3)
Diploma and above	32(32.7%)	66(67.3%)	98 (23.7)
Parity			
Uniparous	84 (71.8%)	59 (28.2%)	143 (34.5)
Multiparous	129 (43.4%)	168 (56.6%)	297 (71.7)
Unintended pregnancy			
Yes	86 (88.7%)	11 (11.3%)	97 (23.4)
No	151(47.6%)	166 (52.4%)	317 (76.6)
History of previous abortion			
Yes	42 (26.1%)	119 (73.9%)	161 (38.9)
No	210 (83 %)	43 (17%)	253 (61.1)
Over all total time of booking for ANC	252 (60.9%)	162 (39.1%)	414 (100%)

d) *Predictors of late ANC booking of pregnant mothers*

After adjusting for socio-demographic and contextual factors; participants having diploma and above educational background (AOR 1.50, (95% CI, 2.10, 1.51)), being employed (AOR 2.20, (95% CI, 2.73-1.01)), previous history of abortion (AOR 1.56 (95% CI, 2.09-1.73) and urban residency (AOR 2.10 (95% CI, 3.25-1.87)) were identified as major contributing factors for the likely seeking behavior of early ANC services compared to their counter parts. The finding shows that participants with unintended pregnancy (AOR 0.45 (95% CI, 0.34, 0.21)) and having poor knowledge of ANC services (AOR 0.51 (95% CI, 0.71-0.21)) were

contributing factors for less likely booking earlier for ANC follow up compared to their comparable group.

Table 2: Predictors of late ANC booking of pregnant mothers in ArtumaFursi district, Ethiopia, 2017(n=414)

Variables	Late book for ANC services		COR (95.5% CI)	P-value	AOR (95% CI)	P-value
	Yes: n (%)	No: n (%)				
Marital status						
Divorced/window/separated	19 (73.1%)	7 (26.9%)	4.67 (1.96-11.52)	0.001		
Unmarried	103 (83.1%)	21 (16.9%)	1.02 (.65-1.58)			
Married	130 (49.2%)	134 (50.8%)	1			
Educational status						
Diploma and above	32 (32.7%)	66 (67.3%)	2.64 (3.33-2.22)	0.002	1.50 (2.10-1.51)	0.001
Secondary	59 (73.8%)	21 (26.2%)	.33 (.18-.611)			
Primary	66 (75.9%)	21 (24.1%)	1.11 (.59-2.08)			
Never been to school	137 (92%)	12 (8%)	2.41 (.20-.84)			
Occupation						
House wife	241 (94.9 %)	13 (5.1%)	1			
Employed	11 (6.9 %)	149 (93.1%)	3.04 (4.58-2.02)	0.0001	2.20 (2.73-1.01)	0.02
Residency						
Rural	198	67				
Urban	54	95	6.51 (8.12-4.34)	0.003	4.53 (7.31-2.57)	0.001
Unintended pregnancy						
Yes	86 (88.7%)	11 (11.3%)	0.61 (5.10-2.95)	0.002	0.45 (0.34-0.21)	0.001
No	151 (47.6%)	166 (52.4%)	1			
Previous history of Abortion						
Yes	42 (26.1%)	119 (73.9%)	3.12 (4.71-3.01)	0.002	1.56 (2.09-1.73)	0.013
No	210 (83 %)	43 (17%)	1			
Number of ANC follow up						
One	101 (55.2%)	82 (44.8%)	4.17 (5.12-2.05)	0.04		
Two	83 (64.8%)	45 (35.2%)	2.89 (8.03-4.09)			
Three	49 (62%)	30 (38%)	5.43 (4.74-1.23)			
More than three	19 (79.2%)	5 (20.8%)	1			
Knowledge of ANC						
Good	18 (14.6%)	105 (85.4%)	1			
Poor	234 (80.4%)	57 (19.6%)	0.75 (0.91-0.23)	0.003	0.51 (0.71-0.21)	0.002

IV. DISCUSSION

This study provides prevalence and identify determinant factors for late ANC booking of pregnant mothers in ArtumaFursi district, Ethiopia.

The findings revealed that late ANC booking among the study units was massive. Out of the total, majority 252 (60.9%) booked late for antenatal care. However, previous studies conducted in Addis Ababa and Zambia showed that about 59.8% and 72% mothers booked early for ANC services respectively [6, 7]. This variation might be due to the residence of study participants since; most of the mothers in this study were rural residents. The other possible explanation for this huge difference might be the deployment of health care professionals because; most of health cadres prefer to work in urban areas.

In this study, educational and occupational status of the participants was the most determinant factors influencing ANC booking time. Both employed and highly educated women had booked earlier than their counter parts. Whereas, those who had never been to school and housewives had booked late for ANC

accounting 92% and 94.9% respectively. This finding is similar with studies conducted in East Wollega, Bangladesh Nigeria and Tanzania [5, 8, 9, 10, 11].

About 73.9% of uniparous mothers booked lately for antennal care compared to multiparous ones. This finding is similar with studies conducted in other parts of Ethiopia, Tanzania and India [7, 9, 12, 13, 14].

Previous obstetricchi story of mothers also determine the time of ANC service seeking. Among women who had history of abortion, majority 73.9% of them visited health institutions for ANC service earlier compared to their counter parts. The finding is concurrent with studies conducted in Ethiopia and Zimbabwe [12, 15, 16].

Unintended pregnancy and lack of good knowledge about antenatal care were other factors to determine the time of ANC service seeking behavior. Those mothers who had had unintended pregnancy (88.7%) and had poor knowledge (80.4%) were too late for initiation of ANC service booking. These findings are parallel with similar studies conducted in Uganda, Malawi Zambia and other parts of Ethiopia [6, 9, 17, 18].



V. CONCLUSION

The magnitude of late booking for ANC service was huge among study participants. Of the total, majority 252 (60.9%) of women were lately booked for ANC services. Additionally, low educational status, being a house wife, rural residency, having poor knowledge of ANC services and unintended pregnancy were pertinent factors for late antenatal care booking. Generally, early ANC service seeking behavior of study participants is very low hence, it needs attention.

VI. RECOMMENDATIONS

Information education and communication (IEC) about on time booking for ANC services targeting women and their partners in the district should be undertaken through multi-cultural, religious leaders and community involvement perspectives. It's better to consider integrating health education of ANC with other health care services holistically. Integrating health education with other services, information dissemination about advantage of early ANC visit should be implemented. Simultaneously, establishing pregnant mothers' group discussion forum about ANC, creating and using Health Development Army (HAD) with high participation of reproductive age women "for the community by the community" must be considered by both governmental and non-governmental organizations co-operatively.

Limitation of the study: This study used only institutional based cross sectional study design in three health institutions i.e. two health centers and one private clinic in a single district.

Abbreviations

ANC -Antenatal Care, EDHS-Ethiopia Demographic Health Survey, FANC-Focused Ante-Natal Care, HAD-Health Development Army, HIV-Human Immune Virus, IEC-Information education and communication, NGO-Nongovernmental Organization, MH₄SRH Mobile Health for Sexual and Reproductive Health, WHO-World Health Organization.

Declarations

Ethics and consent to participate

Ethical clearance and permission was obtained from Wollo University Institutional Research Review Board. Written consent was taken to participate in this research.

Consent to publish

Not applicable.

Availability of data and materials

The materials and data shall be obtained upon request of corresponding author.

Competing interest

The authors declared that there is no any competing interest.

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Authors' contribution

All authors, Ayana Chimdessa, Nathan Estifanos and Jote Markos involved from the inception of idea to the design, analysis and preparation of manuscript.

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Development and Validation of an Instrument to Assess Nurse Practitioners Knowledge towards Use of High Risk/High Alert Medications

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Design: Prospective methodological program.

Methods: The instrument on HRM was developed in the form of videos compatible in both PC and mobile format. The five chapters were emphasised and modules was ensured to be important, relevance, reactions, appropriate with the help of content and face validations. Further, confirmed to be sensitive enough to distinguish the knowledge levels of nurses.

Keywords: *high risk medications, medication error, content validity, reliability, instrument development, instrument validation.*

GJMR-K Classification: NLMC Code: QV 701



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Development and Validation of an Instrument to Assess Nurse Practitioners Knowledge towards Use of High Risk/High Alert Medications

Balakeshwa Ramaiah [✉], Saroj Poudel [✉], Sejal Sharma [✉] & Raju Koneri [✉]

Abstract- Background: Nurse practitioners play an important role in the chain of drug administration process. Adequate updated knowledge is prerequisite to deliver high quality health care services.

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Results: The content validity included six experts involving senior consultants, nurse administrators and pharmacy heads whereas face validity was carried out with the involvement of forty five nurses practitioners. The five point Likert scale was carried out for all the five chapters to receive an average score above four points with Content Validity Index (CVI) = 0.83 and Item-level content validity index (S-CVI) = 0.83. Therefore, suggests the conciseness, appropriateness, and importance of the training materials. The face validity strongly highlighted the approval of the design of instrument and the importance of the issues to the nursing profession. The K-R 20 index consistently reached the score of 0.89 for introduction of HRM, 0.70 for inappropriate abbreviations, 0.85 for dose calculations, 0.79 for storage and labelling and 0.73 for LASA, indicated that the video materials prepared were effective, feasible and attractive.

Conclusions: The validated instrument was found to be appropriate, concise and important to improve the knowledge and handling of nurse practitioners on the HRM (s), thus helps to contribute to better patient care.

Keywords: high risk medications, medication error, content validity, reliability, instrument development, instrument validation.

I. INTRODUCTION

High risk medications (HRM) or high alert medications (HAM) refers to medications which possess narrow therapeutic index or lesser margins of safety and stands a heightened risk of causing substantial harm to patient if used in error. Although, medication errors involving this type of medications are less common, but the consequences to the patient can be more devastating. So, the institute for safe medicinal practices (ISMP 2003) reports high risk medications as drugs which has been frequently involved in either injury, damage or even death of the patients (Engels and Ciarkowski, 2015). The medications such as heparin, warfarin, insulin, sedatives, and narcotics were repeatedly administered by the nurses are reflected as potential drug classes eligible for continuous monitoring. According to American Pharmaceutical Association, HRM or HAM were listed into eight categories such as anticoagulants drugs, chemotherapeutics agents, cardiovascular drugs, opiates, narcotics, benzodiazepines, electrolytes and neuromuscular blocking agents (Cohen, 2007).

According to US pharmacopeia (2001-2006), 60 % of errors have occurred because of anticoagulants and alarmingly, about 3 % of the errors had been associated with deaths. Interestingly, a study done from January 1997 to December 2007 reported 446 medication errors. Among drug classes contributing to this error, anticoagulants consisted of 7 % in which two-thirds of the patients received heparin. Unfortunately, this study reported 28 deaths and 6 patients being suffered from loss of function (Anderson and Townsend, 2015). The use of concentrated electrolyte solutions such as potassium chloride (KCL), along with anticoagulants and cardiovascular drug was reported with potentials adverse drug events (ADEs) as indicated by Bates et al., (1995). Subsequently, published literature by Sheu et al., (2009) highlighted 328 drug administration errors. Insulin, oxytocin and KCL, primarily termed as HRMs were considered as the major culprits for these errors. Another study, reported 469 serious medication errors by the researcher Phillips et al., (2001) which involved in largest number of deaths (54.9 %) because of antineoplastic drug, cardiovascular drug and central nervous system products.

Author [✉]: Associate Professor, Karnataka College of Pharmacy, #33/2, Tirumenahalli, Hegde Nagar Main Road, Bengaluru: 560064, Karnataka, India. e-mail: balupharmacy@gmail.com

Author [✉] & [✉]: Department of Pharmacy Practice, Karnataka College of Pharmacy, #33/2, Tirumenahalli, Hegde Nagar Main Road, Bengaluru-560064, Karnataka, India.

Nurses play an important role in drug administration with an aim to deliver high quality care to the patients by minimizing the medication errors. The reduction in administration errors is a demanding challenge and it's hard to formulate appropriate and safer methods for administration of HRMs, particularly in intensive care units and emergency situations. However, an investigation by Greenglod et al., (2003) showed that administration errors was not reduced significantly by replacement of general nurses with qualified nurses. Hence, implementing an educational programme through the various processes can raise nurses' awareness about medication errors and other various medication-related safety issues regarding to HRMs as explicitly described by Elnour et al. (2008). The instrument in the form of teaching modules can enhance nurse's knowledge and attitude toward handling of HRMs, thus influence the quality of patient care they provide.

Several studies have explained that validation and reliability are always been an important factors in social, health and science research for measurement of accuracy and consistency of an instrument. However, the process for validation of instruments is not frequently carried out in developing countries. This has been associated with the shortage of information on these assessments of validation which should have been carried out in the research field. A Nigerian researcher highlighted the significance of both literary and technical meaning through the process of validation and reliability tests and making them as an important procedure in research works. For improving the knowledge and skill

of tests among researchers, various measures and approaches of examining validation and reliability of an instrument remained deliberated in this study (Anderson and Townsend, 2015).

The various international literatures mentioned about the evaluation of nurses knowledge on HRM by using valid and reliable instruments of measurement. To strengthen the above statement, the Taiwanese researcher in 2006 concluded that the learning module prepared by them was proven to be reliable and was validated through Kuder-Richardson Formula 20 (KR-20) for the assessments of nurse's knowledge on HRMs. In the same way, our educative materials plays an important role in assessing the nurse's knowledge in HRM management, hence the educative materials, has been deeply and vigorously developed and validated from various experts. Instruments in clinical research are required to go through the process of validation and reliability (Priscila and Roberta, 2015). Finally, the instrument was developed and validated with measurement of reliability with Kuder-Richardson reliability 20 for its internal consistency (Hsiao and Chen, 2010). This study was aimed on prepare and valid the teaching materials (as video format) to measure the nurse's knowledge regarding HRM or HAM so as to increase the increment in nurses knowledge.

II. METHODS

The study involved prospective methodological program. The summarized study methodology is represented in Figure 1.

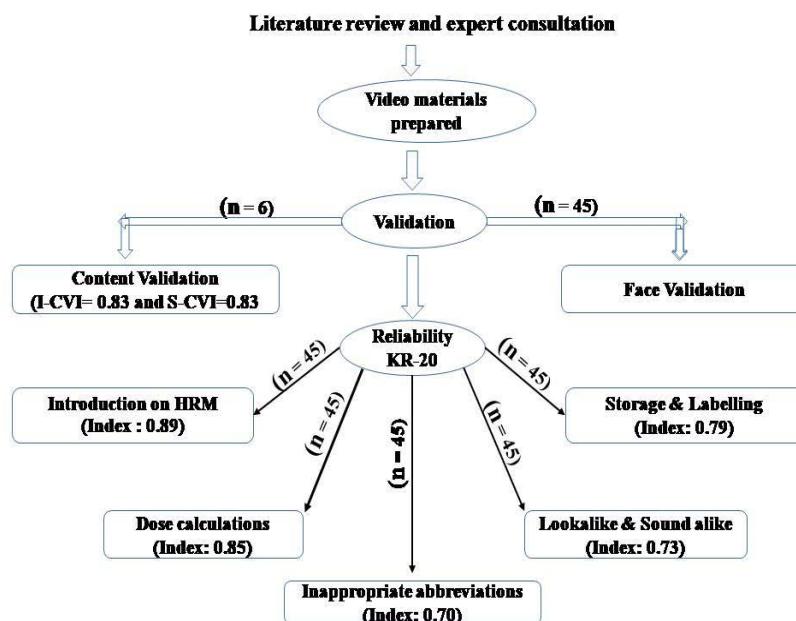


Figure 1: The overall study procedure along with reliability scores

a) *Preliminary preparations for the development of an instrument*

This study mainly includes preparation of educative video materials with rigorous analysis of the collected information, the main purpose of which was to create and validate research instrument and procedures. With respect to Indian nursing practice environment, information required for making educative and training materials were appropriately prepared from global guidelines and HRM management practice. Considering the fact of under stability and comprehensiveness, the materials on high alert medications were prepared. From various sources and literatures articles, five informative and educative chapters viz introduction to HRM, dose calculations, inappropriate abbreviations, look alike and sound alike (LASA) and storage and labelling was prepared. The information was collated and formatted in the form of Microsoft office power point presentation (PPT). The same was validated (out of this study scope) and used for the development of video materials required for this study. A compressed mobile formats, and high resolution personal computer (PC) format materials were made accessible, which would highly favoured and accepted by the participants. The researcher was fully believed that the informative and educative teaching materials made would play an important role for increasing knowledge in nurse practitioners. The materials were prepared for the assembly of data from the participant's responses regarding the training material.

b) *Development of an instrument in the form of video materials*

For the purpose of this study, the information in the training materials was transformed to scripts in the form of narrations in an intention to prepare suitable and appropriate video materials. For easy understandability, language of the scripts was then ascertained for easiest way. By considering various factors like voice of artiste, clarity in tone for pronunciation, rate of speech flow and delivery of speech timing, a suitable voice of female artiste was chosen for recording the well prepared scripts into an audible voice. Under the guidance of supervision of a technical team bearing hands on both recording and editing experience, the whole process was performed in a controlled environment.

The following six crucial processing steps were involved during the development of video materials viz: (i) Recording the scripts into voice in the form of individual sound track (ii) joining of individual sound track to make one single audio file. (iii) Adjust time gap of each slides of PPT with audio files. (iv) Mixing the audio files to each PPT slides. (v) Addition of suitable background sound or tracks to the collaborated files. (vi) Finally, compressing the complete file into suitable PC format as well as mobile format. The software such

as; (i) Audio recorder by Green Apple Studio (Version 1.9.45), (ii) Audacity, The free, Cross-Platform Sound Editor by Audacity Development Team (Version 2.1.3), (iii) Corel Video Studio Ultimate X10 was utilized for the purpose of recording the scripts and collaborating with each slides of ppt. The video was finally ensured to be checked for synchronization and clarity. The prepared video materials were further subjected for validations to ensure its accuracy and reliability.

c) *Instrument validation by using various parameters*

The validation process has its important to research because it's a measurement which measures what it importance to measure. It has estimated through every single element of a construct. The content validity, face validity and reliability are more frequently used as indicators in the process of validation of any training materials. A customized documentation form for the instrument validation was prepared (Annexure 1). The Likert scoring system (1-4) was adopted for rating the each video slide of a chapter and also was used to score overall chapter. The scoring columns for teaching materials in various aspects such as content of the video, clarity of the video and audio as well as various diagrammatic illustrations was assessed. Additionally, the size and duration of the video for each chapter was also validated. The prepared learning modules was ensured to be exposed for the important, relevance, reactions, and appropriateness through the content and face validation, and sensitive enough to distinguish the levels of knowledge of registered nurses.

Forty five nurse practitioners actively involved in the process of the instrument validations. Among them, three were clinical nurses who held positions as head nurses, three of them were from nursing faculty members specialized in clinical teaching on medical and surgical wards, and rest had at least five years of experience as nurse practitioners. The three head nurses and three nursing faculties were utilized as special services for content validity. However, all of them examined the entire instrument, offered their expert opinions and rated the parameters as provided in the documentation form. The final scoring and feedbacks were evaluated and the appropriateness and reliability of the material was finally measured with KR 20. Finally, the validated video materials were distributed among all the station of nurse practitioners to improve their knowledge on HRM.

i. *Content Validity*

Content validity was applied to examine the correctness and suitability of the teaching material (video file). Content validity index (CVI) remains a major concern for the validation of learning modules. Thus, the percentage agreement among specialists for assessing its instrument and its item was obtained by means of CVI calculation. This index permits for the analysis of



each item individually, and subsequently, the instrument as a whole. As mentioned by Lynn (1986), the instrument prepared to be valid follows two types of CVI viz content validity of individual items (I-CVI) and content validity of the overall scale (S-CVI). For I-CVI, the settlement between reviewers concerning on each item of the learning modules as an instrument was measured through the process of Likert scale, with scores that range from one to four (where, 1-irrelevant, 2- slightly relevant, 3- fairly relevant, and 4- completely relevant). Item having the scores of one or two were reviewed or excluded from the test. The results obtained from the I-CVI calculation for each item contained were fairly and completely relevant. So, Lynn (1986) recommends that for the items to be valid an I-CVI should be greater than 0.78 for analyses of instrument by six or more experts.

ii. Face validity

Face validity was conducted to test the effectiveness of the intervention as well as to validate video material. Face validity is defined as a process which includes the expert to be observing the modules of items in the instrument and assenting that the test is a valid for measure of the concept which is being measured just on the face of it. This means researcher are assessing whether each of the measuring items matches any given conceptual domain of the concept. The face validity revealed tough endorsement of the strategy and highlighted the important issues of nurse's profession. The respondents agreed to all training material provided by researcher secure a great atmosphere.

iii. Reliability

The instrument was also subjected to examine whether it had internal consistency. By KR-20 formula, an index score for reliability was calculated as shown in the Formula 1. And appeal about the internal consistency index of reliability to avoid the problems associated over multiple periods of time.

$$r_{KR\ 20} = \left(\frac{k}{k-1} \right) \left(1 - \frac{\sum pq}{\sigma^2} \right) \quad (1)$$

Where, $r_{KR\ 20}$ is the Kuder-Richardson formula 20; k is the total number of test items; \sum indicates to sum; p is the proportion of the test takers who pass an item; q is the proportion of test takers who fail an item; σ^2 is the variation of the entire test.

III. RESULTS AND DISCUSSION

Many suggested strategies have been implemented to describe the errors caused by HRM, so among healthcare professional's high alert medications remains a major concern (Cohen, 2007). In the year 2009, Joint Commission has made a suggestion to avoid the use of misreads, abbreviations and also listed some special precautions which are

needed for LASA. Gladstone (1995) reported that about more than half of life threatening hazard was happened because of rapid proportion of infusion of HRM. The North American system (2006-2008), used a software for reporting medication errors which nearly shows about 7 % of the 443,683 errors occurred by HRM. They also found that higher frequency of medication error occurred at intensive care units (ICUs) compared to clinical or surgical units of hospital. The primary reason being one as ICUs a complex units linked with different severity levels, and different drug groups including HRM. Additionally, the nurse's insufficient knowledge also significantly contributed for the errors (Hsiao and Chen, 2010). The overall reliability of all the chapters in the study is shown in Table 1.

a) Content Validity

The content validity index was reported only in methodological studies because it has focus only for explaining the process of content validations.

i. Item-level content validity Index (I-CVI)

The content validity index was obtained through the process where experts involve in giving a rating of either 3 or 4 (thus represent the main scale into "relevant" and "not relevant"), divided by the total number of experts involved. As shown in Table 2, the mean I-CVI was figured out to be 0.83. As per standard recommendations made by Lynn (1986), the standard can be relaxed when there are six or more than six raters, and also suggest about content validity should not be less than 0.78. The rating could be one "not relevant" rating (I-CVI = 0.83) with six raters or two "not relevant" ratings with nine raters (I-CVI = 0.78). Thus, the mean I-CVI obtained in this study could be considered as an ideal value. Lynn (1986) also suggested that when there is five or fewer experts as participants, there should be an agreement on the content validity for their rating which will be reflected as an equitable. From many published literatures it has been observed that researchers use content validity index information to guide them in reviewing, erasing, otherwise replacing items.

ii. Scale-level content validity Index (S-CVI)

The S- CVI/ave is the combination of number of items of test rated either as extremely or fairly relevant by all experts (x) combined divide by the total number of ratings (i.e 25 divided by 30) from Table 2 and calculated as 0.83. Many researchers (Davis, 1992; Grant & Davis, 1997; Polit & Beck, 2004.) suggest that the value of S-CVI should be of 0.80 or higher, which is consistent in this study. Waltz et al., (2005) mentioned about the average congruency percentage (ACP) which should not be 0.80 (because 0.80 is recommended as standard criterion for acceptability for the S-CVI. Rubio, Berg-Weger, et. al., (2003) mentioned about the development of Caregiver Well-Being Scale through process of content validation, in which they calculated

their S-CVI value based on ratings of relevance given by six judges. They specifically adopted this method because of their concern that with more than six raters, the content validity would be depressed if they used universal approach that demanded all expert agreement. Table 2 shows about the relevance rating of six experts for a five-item scale where all six experts rated 4 out of 5 items as relevant.

The calculation of the S-CVI/Ave involved three ways of methods, which was shown in Table 2. The first as average proportion of items rated relevant by all experts {i.e; S-CVI/Ave as $(.8+.8+.8+.8+.8+1.0)/6 = .83$ }, another way is by summing them and dividing by the number of items: {i.e I-CVIs as $(.83+.83+.83+.83+.83)/5 = .83$ }, a third way is to count the total number of xs in the table (i.e; the number of items rated relevant by all experts combined, which in this case is 25 and to then divide by the total number of ratings: $25/30 = .83$. All three computations will always yield the same results.

They all agreed that the information, rationale, examples and diagrams on the video were vital on managing HRM by nurses and that the whole content was well organized, correct, precise and attractive.

b) Face validity

The face validity was conducted to determine the various aspects of study design which includes whether the instrument as learning materials was applicable, whether the audio and video clarity was clear and audible, whether the diagrammatic representations was clearly visible. Continuing medical education (CME) form of learning modules of HRM were distributed to 45 registered nurses practitioners showing strong approval of the research design, its applicability, clear and comprehensive and the importance of the issue to the nursing profession.

c) Reliability

The process of validity and reliability concepts could be easily misunderstood. A validity symbolises about the accuracy of test whereas reliability denotes a test is reliable when it produces same results under the identical conditions. So that under the same conditions exactly the same experiment can be perform by other researchers, and can generate the same results which strengthen the outcomes and provide guarantee about the inclusive controlled public will consent the premise. Deprived of this repetition of statistically important results, the research has not satisfied almost all of the necessities of testability. The Kuder-Richardson formula 20 (KR20) was always involved as most commonly used formula for estimating the reliability of a test based on internal consistency, also called as reliability coefficient which requires only single test administration.

KR-20 always estimate the internal consistency of test materials (or reliability coefficient) based on the number of items involved in the test, proportion of

correct answers given by candidates and the standard deviation of the total score. The values could range from 0 to 1. The closer the score is to 1, the more reliable the test. The overall test observations used for the reliability (n= 45) was documented in an excel sheet and the correct score per slide for the chapters introduction, dose calculations, inappropriate abbreviations, LASA and storage and labelling was obtained as shown in Tables 3, 4, 5, 6 and 7 respectively. The mean sum of product of proportion passed and proportion failed was calculated to apply standard deviation for each individual chapter. The validation was then done by applying KR-20 reliability formulae. When individual chapters were considered for their reliability, the index was obtained as 0.8994, 0.8587, 0.7077, 0.73736 and 0.7962 for chapters 1 to five, respectively. The reliability score is always expected to be above 0.50.

Similarly, Lin et al., (1999) showed the analysis of internal consistency for KR-20 value was reported in range of 0.86 to 0.94 for multiple choice test items in the registered nurse licensure exam. Also, Hsiao and Chen, 2010 used KR reliability for their true and false tests in development of valid instrument to assess nurse's knowledge of HRM in a tertiary care hospital, and got a value of 0.74, which indicated acceptable reliability. While, Priscila and Roberta, 2015 did the Brazilian transformation of the work done by Taiwanese researchers. Hsiao and Chen, 2010 computed KR 20 formulae for their instrument to assess nurse's knowledge and obtained a value of 0.74 respectively. Shafizan S. et al., (2013) designed an instrument test for students, to examine whether the test items made by researcher ensemble course for university music students and therefore for examining its reliability, they used KR 20 formula, the value of which was obtained as 0.717. Stephen, H., et al., (2017), developed an instructor-mediated performance assessment test, for which they did reliability and obtained an index of 0.95.

IV. CONCLUSION

Errors that occur due to high risk medication can significantly lead to patient harm. Hence, effective strategies are required for the safe use of HAM/HRM. This paper was designed to explain about the development and instrument process of the teaching materials through validity and reliability process that would benefit the nursing practitioners on their prospective about HRM and its management. Thus, the instrument made plays an important role in for making decision and recommendations for those nurses with insufficient knowledge of HRM. As the researcher proven that the training materials be able to promote the nurse's alertness about medication errors and other medication related safety issues. With this concern, instrument in the form of training materials consisting of demanding information on various aspects of HRM



management was prepared and finally validated. The applicability of such instrument in modern world practice effectively transforms the information to health care professionals on real time and in an easier way. Such practices will certainly help in reducing HRM related medication errors through better patient care.

Declarations

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Availability of Data and Materials

Data are available from the corresponding author upon request.

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Table 1: Representation of Index Value and Reliability for the five learning video modules.

Chapter No.	Chapter Name	Index Value	Reliability
1.	Introduction to High Risk Medication	0.8994*	Good
2.	Dose Calculation	0.8587*	Good
3.	Inappropriate abbreviation's	0.7077*	Good
4.	Look-alike Sound-alike drugs	0.7373*	Good
5.	Storage and Labelling	0.7963*	Good
Average		0.79988*	Good

*if the index value is >0.50 the sample is having good reliability

Table 2: Fabricated Ratings on a 5-Item Scale by Six Experts expressed in terms of item-level and scale-level content validity index values.

Item (Chapter)	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in Agreement	I-CVI
Introduction on HRM	-	x	x	x	x	x	5	0.83
Dose Calculation	x	-	x	x	x	x	5	0.83
Inappropriate Abbreviations	x	x	-	x	x	x	5	0.83
LASA Drugs	x	x	x	-	x	x	5	0.83
Storage and Labelling	x	x	x	x	-	x	5	0.83
Proportion Relevant:	0.8	0.8	0.8	0.8	0.8	1.0		
Mean I-CVI= 0.83				Mean S-CVI = 0.83				
*x: Agreements on content by expert, *I-CVI: item-level content validity index *S-CVI: scale-level content validity index								

Table 3: Reliability table for the chapter 'introduction to high risk medication' by KR 20 formula.

Slide Number	Correct Score	Proportion passed	Proportion failed	p*q
1	33	0.73	0.27	0.1971
2	17	0.37	0.63	0.2331
3	13	0.28	0.72	0.2016
4	33	0.73	0.27	0.1971
5	35	0.77	0.23	0.1771
6	34	0.75	0.25	0.1875
7	33	0.73	0.27	0.1971
8	33	0.73	0.27	0.1971
9	32	0.71	0.29	0.2059
10	30	0.64	0.36	0.2304
11	34	0.75	0.25	0.1875
12	28	0.62	0.38	0.2356
13	31	0.68	0.32	0.2176
14	27	0.60	0.40	0.2400
15	26	0.57	0.43	0.2451
16	29	0.64	0.36	0.2304
17	33	0.73	0.27	0.1971
18	35	0.77	0.23	0.1771
19	20	0.44	0.56	0.2464
20	22	0.48	0.52	0.2496
21	33	0.77	0.23	0.1771
22	32	0.71	0.29	0.2059
23	34	0.75	0.25	0.1875
24	35	0.77	0.23	0.1771

Table 4: Reliability table for the chapter “dose calculation” by KR 20 formula.

Slide Number	Correct Score	Proportion passed	Proportion failed	p*q
1	35	0.77	0.23	0.1771
2	26	0.57	0.43	0.2059
3	33	0.73	0.27	0.1971
4	34	0.75	0.25	0.1875
5	26	0.57	0.43	0.2451
6	29	0.64	0.36	0.2304
7	24	0.53	0.47	0.2491
8	35	0.77	0.23	0.1771
9	32	0.71	0.29	0.2059
10	33	0.73	0.27	0.1971
11	34	0.75	0.25	0.1875
12	28	0.62	0.38	0.2356
13	22	0.48	0.52	0.2496
14	29	0.64	0.36	0.2304
15	26	0.57	0.43	0.2451
16	29	0.64	0.36	0.2304
17	33	0.73	0.27	0.1971
18	19	0.42	0.58	0.2436
19	20	0.44	0.56	0.2464
20	22	0.48	0.52	0.2496

Mean Sum of p*q: 4.8962; Standard deviation squared: 26.5763
Index value $r_{KR20} = \left(\frac{k}{k-1} \right) \left(1 - \frac{\sum pq}{\sigma^2} \right)$: 0.8587

Table 5: Reliability table for the chapter “inappropriate abbreviations” by KR 20 formula.

Slide Number	Correct Score	Proportion passed	Proportion failed	p*q
1	25	0.55	0.45	0.2475
2	26	0.57	0.43	0.2451
3	29	0.66	0.34	0.2244
4	25	0.55	0.45	0.2475
5	26	0.57	0.43	0.2451
6	29	0.64	0.36	0.2304
7	24	0.53	0.47	0.2491
8	26	0.57	0.43	0.2451
9	22	0.48	0.52	0.2496
10	30	0.66	0.34	0.2240
11	25	0.55	0.45	0.2475
12	28	0.62	0.38	0.2356
13	26	0.57	0.43	0.2451
14	29	0.64	0.36	0.2304
15	29	0.64	0.36	0.2304
16	26	0.57	0.43	0.2451
17	30	0.66	0.34	0.2240

Mean Sum of p*q: 3.9488; Standard deviation squared: 13.5073
Index value $r_{KR20} = \left(\frac{k}{k-1} \right) \left(1 - \frac{\sum pq}{\sigma^2} \right)$: 0.7077



Table 6: Reliability table for the chapter “lookalike and sound-alike medications” by KR 20 formula.

Slide Number	Correct Score	Proportion passed	Proportion failed	p*q
1	35	0.77	0.23	0.1771
2	20	0.44	0.56	0.2464
3	22	0.48	0.52	0.2496
4	33	0.77	0.23	0.1771
5	32	0.71	0.29	0.2059
6	34	0.75	0.25	0.1875
7	35	0.77	0.23	0.1771
8	33	0.73	0.27	0.1971
9	25	0.55	0.45	0.2475
10	28	0.62	0.38	0.2356
11	24	0.53	0.47	0.2491
12	35	0.77	0.33	0.1771
13	32	0.71	0.29	0.2059
14	33	0.73	0.27	0.1971
15	31	0.68	0.32	0.2176
16	25	0.55	0.45	0.2475
17	28	0.62	0.38	0.2356
18	29	0.64	0.36	0.2304
19	24	0.53	0.47	0.2491
20	35	0.77	0.33	0.2541
21	26	0.57	0.43	0.2451
22	29	0.64	0.36	0.2304
23	24	0.53	0.47	0.2491
24	29	0.64	0.36	0.2304
25	32	0.71	0.29	0.2059
26	30	0.66	0.34	0.2240

Mean Sum of p*q: 5.7493; Standard deviation squared: 19.7553

Index value $r_{KR20} = \left(\frac{k}{k-1} \right) \left(1 - \frac{\sum pq}{\sigma^2} \right)$: 0.73736

Table 7: Reliability table for the chapter “storage and labelling of medications” by KR 20 formula.

Slide Number	Correct Score	Proportion passed	Proportion failed	p*q
1	33	0.73	0.27	0.1971
2	32	0.71	0.29	0.2059
3	34	0.75	0.25	0.1875
4	35	0.77	0.23	0.1771
5	26	0.57	0.43	0.2451
6	29	0.64	0.36	0.2304
7	33	0.73	0.27	0.1971
8	35	0.77	0.23	0.1771
9	20	0.44	0.56	0.2464
10	22	0.48	0.52	0.2496
11	34	0.75	0.25	0.1875
12	33	0.73	0.27	0.1971
13	33	0.73	0.27	0.1971
14	32	0.71	0.29	0.2059
15	30	0.64	0.36	0.2304
16	34	0.75	0.25	0.1875
17	28	0.62	0.38	0.2356
18	31	0.68	0.32	0.2176
19	27	0.60	0.40	0.2400
20	30	0.64	0.36	0.2304

Mean Sum of p*q: 4.2224; Standard deviation squared: 17.4184

Index value $r_{KR20} = \left(\frac{k}{k-1} \right) \left(1 - \frac{\sum pq}{\sigma^2} \right)$: 0.7962





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Nutrition and Chronic Diseases among Makkah Visitors

By Omar B Ahmed, Tariq A Al Malki, Arwa AAl Malki & Anas S Dablood

Umm Al-Qura University

Abstract- Chronic conditions are thought to affect a high number of the general population of pilgrims and Umrah visitors. With a little planning and preparation, people with chronic illnesses should have safe and enjoyable Umrah rituals. The study aimed to characterize the association between chronic diseases and dietary regimens among Umrah visitors. Data collection questionnaire designed for recording of the most expected diseases among Umrah visitors. The results showed that out of 401 Umrah visitors suffering from chronic diseases, 80.8% of them were on medication. The most disease was diabetes mellitus (41.4%) followed by blood hypertension (31.9%), chronic respiratory disease (18.5%) and chronic heart diseases (6.5%). Also, 44.9% of them were doing Umrah for the second time of their life, and 59.6 % of the patients had a special food program. Statistically, there was a significant association between age and the type of chronic disease (p -value <0.05), while there was no significant difference between the existing chronic disease in male and female and the type of the food taken by Umrah visitors (p -value > 0.05).

Keywords: makkah, umrah visitors, travelers, chronic diseases, nutrition.

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NUTRITION AND CHRONIC DISEASES AMONG MAKKAH VISITORS

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Nutrition and Chronic Diseases among Makkah Visitors

Omar B Ahmed ^a, Tariq A Al Malki ^a, Arwa AAI Malki ^b & Anas S Dabool ^c

Abstract- Chronic conditions are thought to affect a high number of the general population of pilgrims and Umrah visitors. With a little planning and preparation, people with chronic illnesses should have safe and enjoyable Umrah rituals. The study aimed to characterize the association between chronic diseases and dietary regimens among Umrah visitors. Data collection questionnaire designed for recording of the most expected diseases among Umrah visitors. The results showed that out of 401 Umrah visitors suffering from chronic diseases, 80.8% of them were on medication. The most disease was diabetes mellitus (41.4%) followed by blood hypertension (31.9%), chronic respiratory disease (18.5%) and chronic heart diseases (6.5%). Also, 44.9% of them were doing Umrah for the second time of their life, and 59.6 % of the patients had a special food program. Statistically, there was a significant association between age and the type of chronic disease (p -value <0.05), while there was no significant difference between the existing chronic disease in male and female and the type of the food taken by Umrah visitors (p -value > 0.05). It was concluded that those with chronic diseases should obtain a great deal of information and advice from a travel specialist doctor, and it is important that healthy foods to be promoted at the visitors food services centers.

Keywords: makkah, umrah visitors, travelers, chronic diseases, nutrition.

I. INTRODUCTION

Chronic disease is a disease that persists for three months or more [1]. Generally, there are slow in progression and long in duration. There are many types of chronic diseases such as; diabetes, cardiovascular such as heart attacks and stroke, cancers diseases in addition to the chronic respiratory condition such as chronic obstructed pulmonary disease (COPD) and asthma diseases [2]. Generally, vaccines or medication cannot prevent chronic diseases. Furthermore, chronic diseases cannot communicate from person to person [3]. Travel medicine is a specialty that needs highly specialized persons in travel-related diseases, In addition to up-to-date knowledge of the worldwide epidemiology of diseases or conditions [4]. Worldwide, rates of international travel are growing continuously, about 1

Author a: The Custodian of the Two Holy Mosques Institute for Hajj and Umrah Research, Umm Al-Qura University, Saudi Arabia.

e-mail: abuaglah1@hotmail.com

Author a: Public Health Program, Ministry of Health, Makkah.

Author b: Ministry of Health, Saudi Arabia.

Author c: Department of Public Health, College of Health Science, Umm Al Qura University, Alain, Saudi Arabia.

billion travelers worldwide crossing international boundaries yearly [5]. In Saudi Arabia, the number of pilgrims in 2018 attracted more than 3 million pilgrims from 184 countries [6]. Increasing globalization in travel leads to increase the risk of travel-related illnesses and progress pre-existing health problems such as chronic disease. A traveler's health depends on providing pre-travel counseling on appropriate interventions to promote health and prevent adverse health outcomes during travel [7, 8]. Unfortunately, a small number of travelers will seek pre-travel health advice. Lack of awareness among travelers is not being insured under health plans. Furthermore, those travelers who are consulting practitioners who are not eligible trained to recommend patients on travel [9, 10, 11, 12]. Some studies suggest that pre-travel care should be achieved by a certificated practitioners in the field of travel medicine (i.e., provided by local or international society of travel medicine) [13]. Progressive of chronic disease may kill three in five people worldwide and then becomes a leading cause of mortality in the world by representing 60% of all deaths. Moreover, it causes great socioeconomic problems within all countries, particularly developing nations [2, 14]. In developed countries such as United State of America (USA), 88% of Americans over 65 years have at least one chronic disease [1]. On the other hand, poor diet is a contributor cause to chronic diseases and possibly the death in USA [15]. Nutritional treatment in early stages of chronic kidney disease could prolong life [16]. Malnutrition and protein-energy wasting has been demonstrated to be strongly related to mortality in chronic kidney disease patients [17] [18]. During traveling, chronic disease care has become more complicated because easily access to highly processed foods and low consumption of fresh food [19]. The increasing physical activity and reducing intakes of highly rich foods with drinks in sugars can prevent unhealthy weight gain. More recent studies have not shown much improvement in the low prevalence of healthy lifestyle practices [20, 21]. Moreover, studies have shown that clinicians' knowledge and counseling about healthy diets are lacking [22]. That is may be due to difficulties for diabetic patients to find the recommended nutrient intakes described within dietary guidelines. The efforts of individuals and their healthcare providers, strategies to increase the nutritional quality of prepared foods could gain improved widespread benefits [23] [24]. Finally, CDC (Centers for Disease



Control and Prevention) provide health information for International Travel commonly called the Yellow Book published every two years as a reference for health professionals providing care to international travelers [25]. The study aimed to characterize the association between chronic diseases and dietary regimens among Umrah visitors during the first Umrah season in 1439.

II. MATERIALS AND METHODS

The study conducted at Holy City of Makkah Al Mukarramah, during Umrah season that at the first months of 1439 (1st September till 31th of December 2017). Inclusion criteria were simple random 401 travelers (Umrah visitors) using data collection questionnaire designed for recording of the most expected chronic diseases among Umrah visitors, while the exclusion criteria were non-Umrah visitors. Socio-demographic characteristics were age, level of education, job, marital status, education, job, socio economic status, Medical history and nutritional survey (Weather participant take white or brown rice and bread, low or whole dairy products, low-fat meat or chicken, low-sugar or regular beverage, fresh or canned salty food, well-cooked or raw food). Data entry and statistical analysis were done using SPSS 21.0 program.

III. RESULTS AND DISCUSSION

Travel to Makkah can be relaxing and rewarding, but people with chronic may face unique challenges when they travel overseas, but sometimes the physical demands of travel can be stressful. The present study outlined most common chronic diseases and their dietary regimens during the first Umrah season in 1439 (2017). Four hundred and one were the Umrah visitors who declared that they had chronic diseases, most of them (65.38%) were male (Figure 1) while (65.38%) married (Figure 2). About 60.6% of the patients were from the age group 21-40 years old; none were more than 80 years (Figure 3). The present study showed that most of the Umrah visitors were with educational secondary school level (62.1%) while 37.4% of them were of university educational level of or higher (Figure 4). The commonest nationality of Umrah visitors with chronic diseases was Saudi (21.7%), followed by Bangladesh (19.7%) and Egyptian (14.4%) (Figure 5). The results of the present study were closed to previous studies (28) which showed Saudi citizens represented 42.5% of the total patients where the incidence in Saudi patients was more than that in other nationalities. The present study showed that the commonest chronic disease encountered among Umrah visitors was Diabetes Mellitus (41.4%), followed by blood hypertension (31.9%), chronic respiratory disease (18.5%) and chronic heart disease (6.5%) inflammatory bowel syndrome (1%) (Figure 6).

Another study reported that residents with a history of migration with a higher prevalence of chronic

diseases such as cardiac diseases, hypertension, and diabetes (26). Statistically, the present study showed a significant association between age and the type of chronic disease (p -value <0.05), also there was no significant association between the chronic diseases and the gender (p -value > 0.05). Diabetes leads to the increased risk of many diseases such as cardiovascular diseases, kidney disease, stroke, and infections. Cardiovascular diseases are major etiologic morbidity factors in the world due to unbalanced diets and physical inactivity. More than half of international travelers to developing countries become ill during their trip, hence a small number looks for medical care for a travel-associated illness during their travel (27). So any chronic case, such as diabetes, blood pressure or kidney disease may add challenges to the traveler. Planning is the key to a successful Umrah visit trip. Bone disease is a problem of older people. Adequate intakes of calcium and vitamin D in patients with high osteoporosis rates may help to reduce fracture risk. Also, the sun exposure and physical activity may strengthen bones and muscles. The highest frequency of Umrah visits (44.9%) among Umrah visitors was for the second time per year, and 24.4% had an average annual visit frequency of 3 times (Figure 7). In the present study 80.8% of the patients on medication (Figure 8). In the present study (39.9%) the Umrah visitors traveled to Makkah without consulting a specialist doctor. Also 31.7% of them used to make regular medical check only once time before traveling while 28.4% of them used to make a medical check for two times (Figure 9). Most participants (72.1%) used to do periodic laboratory and measurement tests (Figure 10). Each Umrah visitor needs to schedule an appointment with a travel specialist doctor as soon as possible and may ask for additional health needs, travel requirements. Also, he may be asked to do medical investigation and to bring extra medication packed in visitors carry-on luggage. Medications purchased abroad may not meet Saudi standards. Also, the study showed, most of the visitors were on medication. Hence, it is very important to consider bringing copies of visitors prescriptions, wearing a medical alert bracelet and a first aid kit packed with over the counter medications approved by the physician. Also, 59.6% of the patients had a diet food program (Figure 11). Also, 78.3% used only white bread/rice for eating (Figure 12) and while 71.1% and 28.9% had chicken/ meat with regular and low fat in their meals, respectively (Figure 13), also 62.3% and 37.7% of them were had regular and low fat a dairy product within their meals, respectively (Figure 14) and 71.1% and 28.9% of them were had regular and low sugar beverage product, respectively (Figure 15). The rapidly increasing burden of chronic diseases is a determinant of global public health. For healthy diets, healthy foods should be promoted at Umrah visitors food services. For diabetic

patients, overweight and obesity and physical inactivity may raise the rates of type 2 diabetes. During traveling, increased physical activity and maintaining a healthy weight can prevent and help the treatment of diabetes. Risk of chronic diseases such as heart disease and stroke is reduced by eating low saturated fats, enough amounts of fruits and vegetables and low-salt diets. Also it is very important to practice physical activity and controlling weight. Reduction of salt intake helps to reduce blood pressure and consequently will limit the cardiovascular diseases. Dietary modifications are common treatment plans for patients with different chronic diseases. It was supposed that the patient who read labels on the food packages used less energy, low saturated fat, carbohydrates, and sugar, and more fibers than those who did not (29). Such findings reflect the value of dietary counseling in chronic disease management (29). The present study showed no significant association between the chronic diseases and the type of food taken by Umrah visitors (p -value > 0.05). The study concluded that chronic diseases among Umrah visitors are variable. Also, it could be recommended that those with chronic disease should obtain a great deal of information and advice from a travel specialist doctor and may need to carry extra medication. Also, healthy foods should be promoted at Umrah visitor's food services.

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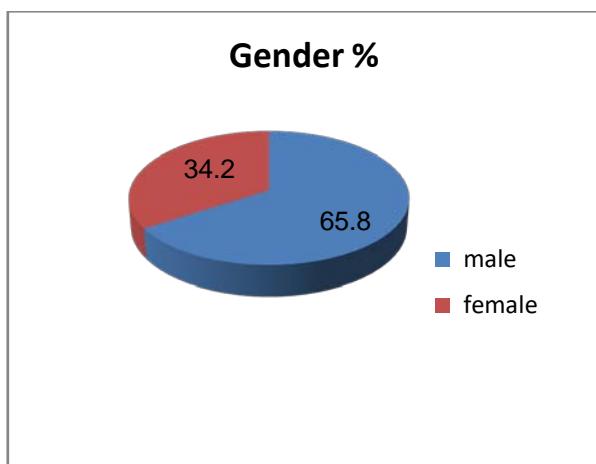


Figure 1: Frequency of gender

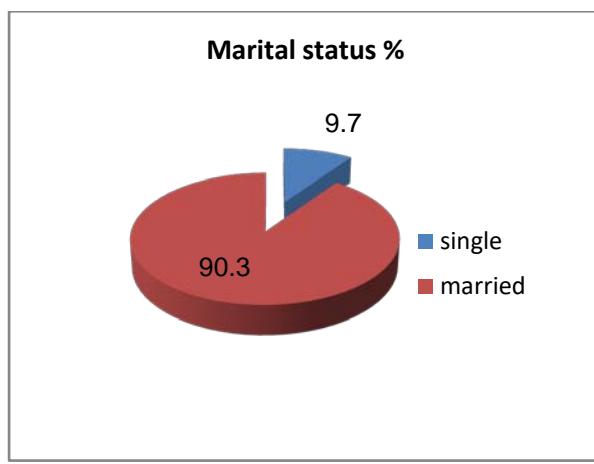


Figure 2: Frequency of married patients

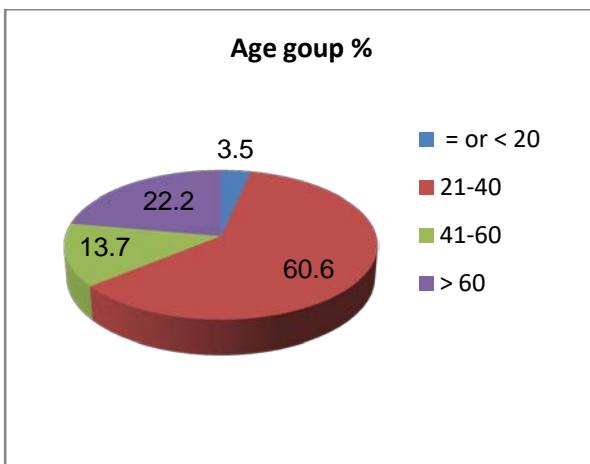


Figure 3

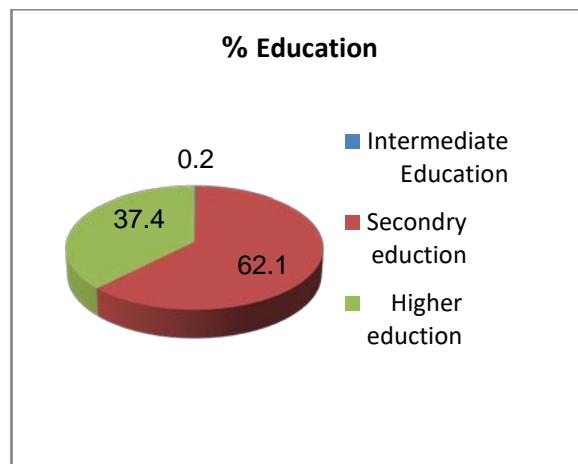


Figure 4

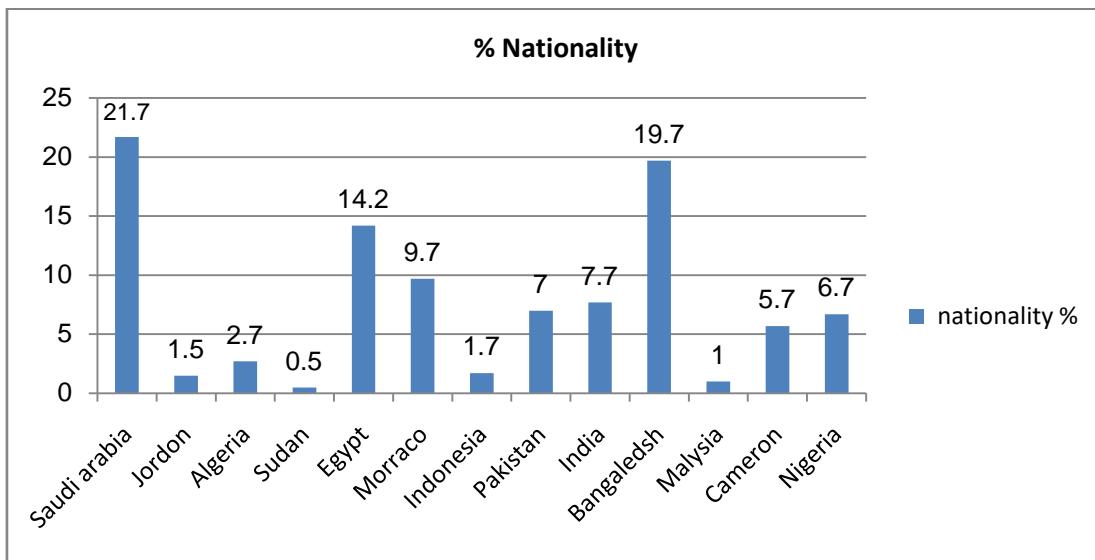


Figure 5: Distribution of chronic diseases according to nationality

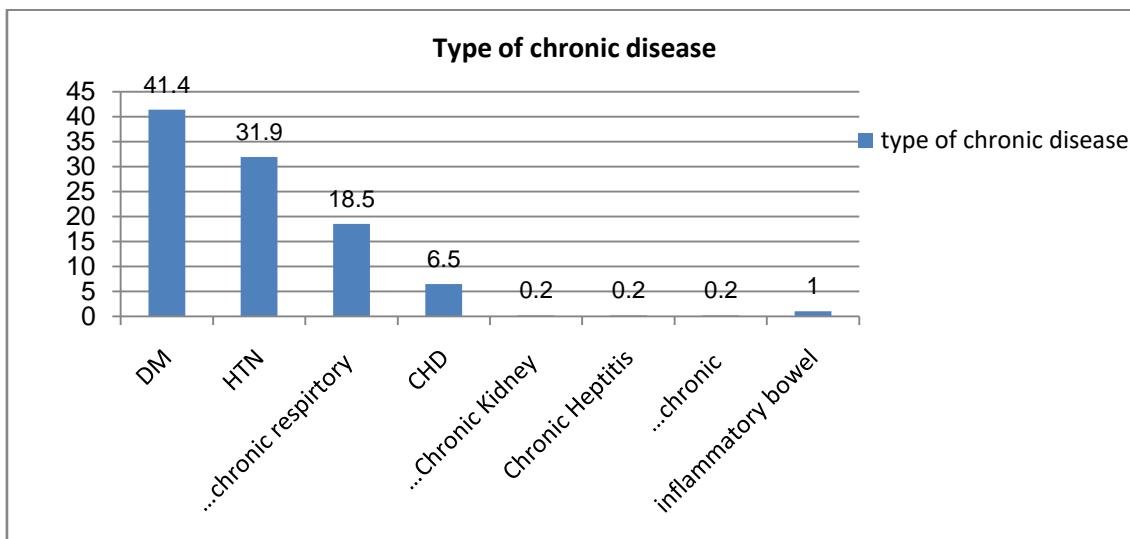


Figure 6: Type of chronic disease %

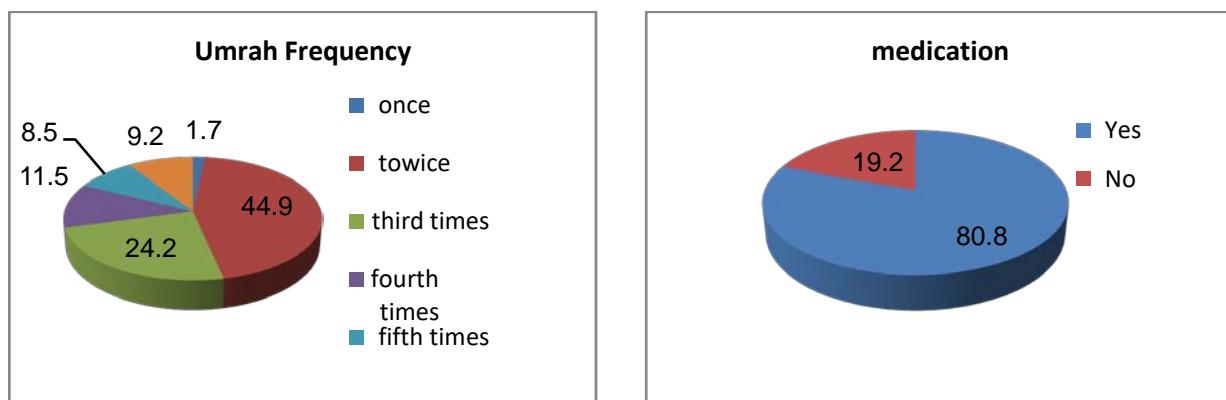


Figure 7: Umrah Frequency %

Figure 8: Medication %

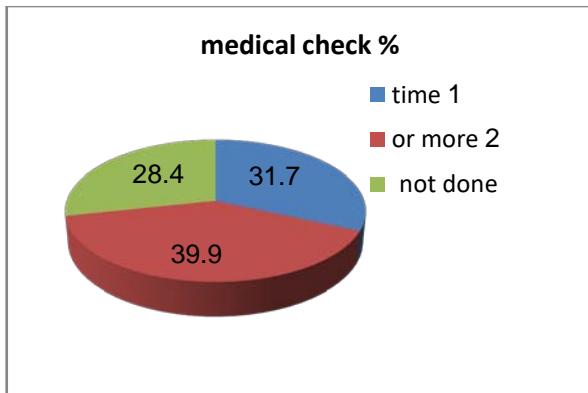


Figure 9: Frequency of medical check

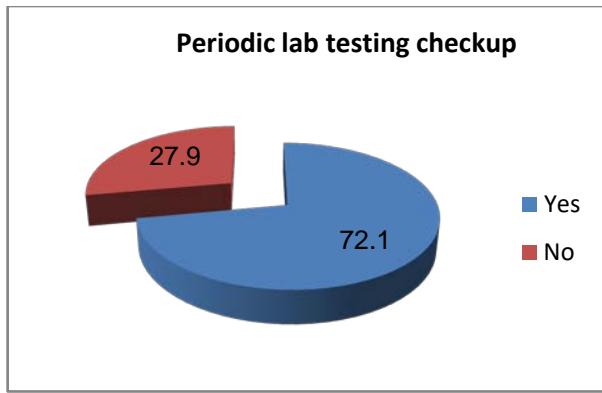


Figure 10: Periodic lab testing checkup %

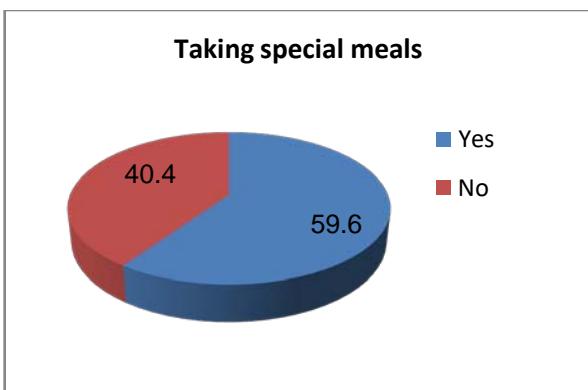


Figure 11: Taking special meals %

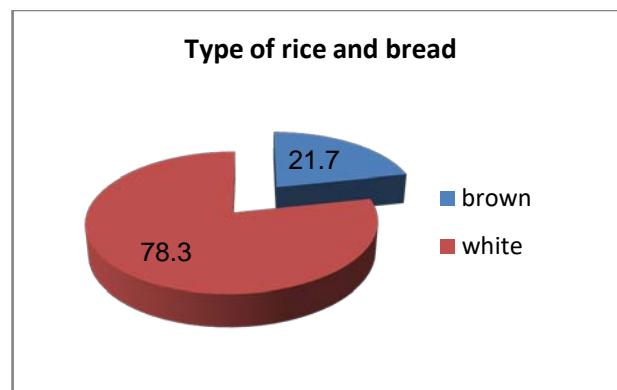


Figure 12: Type of rice and bread %

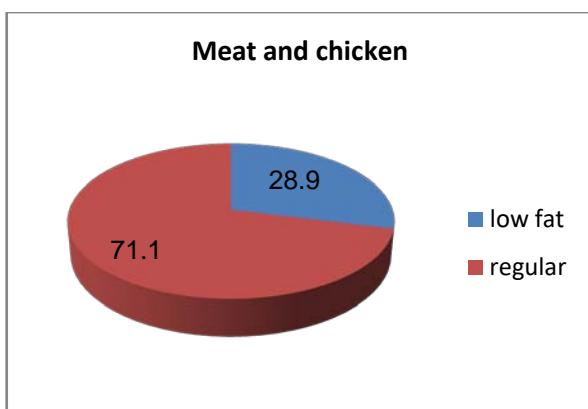


Figure 13: Meat and chicken %

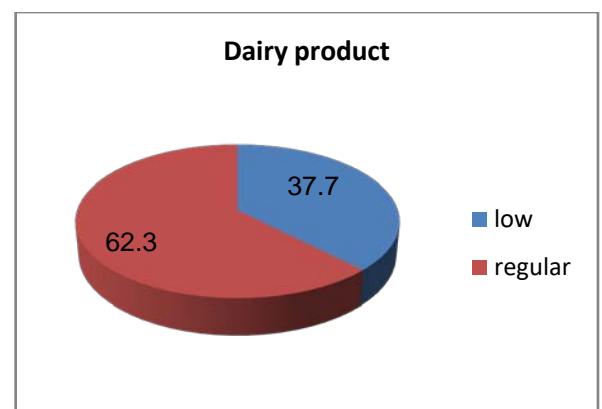


Figure 14: Dairy product %

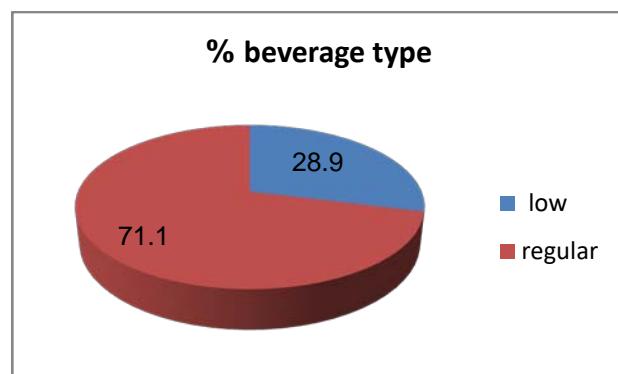


Figure 15: Beverage product type

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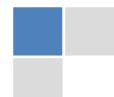


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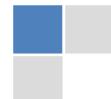
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Authors are advised to submit any mathematical equation using either MathJax, KaTeX, or LaTeX, or in a very high-quality image.

Tables, Figures, and Figure Legends

Tables: Tables should be cautiously designed, uncrowned, and include only essential data. Each must have an Arabic number, e.g., Table 4, a self-explanatory caption, and be on a separate sheet. Authors must submit tables in an editable format and not as images. References to these tables (if any) must be mentioned accurately.



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Figures are supposed to be submitted as separate files. Always include a citation in the text for each figure using Arabic numbers, e.g., Fig. 4. Artwork must be submitted online in vector electronic form or by emailing it.

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TIPS FOR WRITING A GOOD QUALITY MEDICAL RESEARCH PAPER

1. Choosing the topic: In most cases, the topic is selected by the interests of the author, but it can also be suggested by the guides. You can have several topics, and then judge which you are most comfortable with. This may be done by asking several questions of yourself, like "Will I be able to carry out a search in this area? Will I find all necessary resources to accomplish the search? Will I be able to find all information in this field area?" If the answer to this type of question is "yes," then you ought to choose that topic. In most cases, you may have to conduct surveys and visit several places. Also, you might have to do a lot of work to find all the rises and falls of the various data on that subject. Sometimes, detailed information plays a vital role, instead of short information. Evaluators are human: The first thing to remember is that evaluators are also human beings. They are not only meant for rejecting a paper. They are here to evaluate your paper. So present your best aspect.

2. Think like evaluators: If you are in confusion or getting demotivated because your paper may not be accepted by the evaluators, then think, and try to evaluate your paper like an evaluator. Try to understand what an evaluator wants in your research paper, and you will automatically have your answer. Make blueprints of paper: The outline is the plan or framework that will help you to arrange your thoughts. It will make your paper logical. But remember that all points of your outline must be related to the topic you have chosen.

3. Ask your guides: If you are having any difficulty with your research, then do not hesitate to share your difficulty with your guide (if you have one). They will surely help you out and resolve your doubts. If you can't clarify what exactly you require for your work, then ask your supervisor to help you with an alternative. He or she might also provide you with a list of essential readings.

4. Use of computer is recommended: As you are doing research in the field of medical research then this point is quite obvious. Use right software: Always use good quality software packages. If you are not capable of judging good software, then you can lose the quality of your paper unknowingly. There are various programs available to help you which you can get through the internet.

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7. Revise what you wrote: When you write anything, always read it, summarize it, and then finalize it.

8. Make every effort: Make every effort to mention what you are going to write in your paper. That means always have a good start. Try to mention everything in the introduction—what is the need for a particular research paper. Polish your work with good writing skills and always give an evaluator what he wants. Make backups: When you are going to do any important thing like making a research paper, you should always have backup copies of it either on your computer or on paper. This protects you from losing any portion of your important data.

9. Produce good diagrams of your own: Always try to include good charts or diagrams in your paper to improve quality. Using several unnecessary diagrams will degrade the quality of your paper by creating a hodgepodge. So always try to include diagrams which were made by you to improve the readability of your paper. Use of direct quotes: When you do research relevant to literature, history, or current affairs, then use of quotes becomes essential, but if the study is relevant to science, use of quotes is not preferable.

10. Use proper verb tense: Use proper verb tenses in your paper. Use past tense to present those events that have happened. Use present tense to indicate events that are going on. Use future tense to indicate events that will happen in the future. Use of wrong tenses will confuse the evaluator. Avoid sentences that are incomplete.

11. Pick a good study spot: Always try to pick a spot for your research which is quiet. Not every spot is good for studying.

12. Know what you know: Always try to know what you know by making objectives, otherwise you will be confused and unable to achieve your target.

13. Use good grammar: Always use good grammar and words that will have a positive impact on the evaluator; use of good vocabulary does not mean using tough words which the evaluator has to find in a dictionary. Do not fragment sentences. Eliminate one-word sentences. Do not ever use a big word when a smaller one would suffice.

Verbs have to be in agreement with their subjects. In a research paper, do not start sentences with conjunctions or finish them with prepositions. When writing formally, it is advisable to never split an infinitive because someone will (wrongly) complain. Avoid clichés like a disease. Always shun irritating alliteration. Use language which is simple and straightforward. Put together a neat summary.

14. Arrangement of information: Each section of the main body should start with an opening sentence, and there should be a changeover at the end of the section. Give only valid and powerful arguments for your topic. You may also maintain your arguments with records.

15. Never start at the last minute: Always allow enough time for research work. Leaving everything to the last minute will degrade your paper and spoil your work.

16. Multitasking in research is not good: Doing several things at the same time is a bad habit in the case of research activity. Research is an area where everything has a particular time slot. Divide your research work into parts, and do a particular part in a particular time slot.

17. Never copy others' work: Never copy others' work and give it your name because if the evaluator has seen it anywhere, you will be in trouble. Take proper rest and food: No matter how many hours you spend on your research activity, if you are not taking care of your health, then all your efforts will have been in vain. For quality research, take proper rest and food.

18. Go to seminars: Attend seminars if the topic is relevant to your research area. Utilize all your resources.

19. Refresh your mind after intervals: Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.



20. Think technically: Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.

21. Adding unnecessary information: Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.

22. Report concluded results: Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.

23. Upon conclusion: Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium through which your research is going to be in print for the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects of your research.

INFORMAL GUIDELINES OF RESEARCH PAPER WRITING

Key points to remember:

- Submit all work in its final form.
- Write your paper in the form which is presented in the guidelines using the template.
- Please note the criteria peer reviewers will use for grading the final paper.

Final points:

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

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The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to prior workings.

Writing a research paper is not an easy job, no matter how trouble-free the actual research or concept. Practice, excellent preparation, and controlled record-keeping are the only means to make straightforward progression.

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Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

To make a paper clear: Adhere to recommended page limits.



Mistakes to avoid:

- Insertion of a title at the foot of a page with subsequent text on the next page.
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- Submitting a manuscript with pages out of sequence.
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- Keep paying attention to the topic of the paper.
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- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

Title page:

Choose a revealing title. It should be short and include the name(s) and address(es) of all authors. It should not have acronyms or abbreviations or exceed two printed lines.

Abstract: This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite references at this point.

An abstract is a brief, distinct paragraph summary of finished work or work in development. In a minute or less, a reviewer can be taught the foundation behind the study, common approaches to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study with the subsequent elements in any summary. Try to limit the initial two items to no more than one line each.

Reason for writing the article—theory, overall issue, purpose.

- Fundamental goal.
- To-the-point depiction of the research.
- Consequences, including definite statistics—if the consequences are quantitative in nature, account for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

Approach:

- Single section and succinct.
- An outline of the job done is always written in past tense.
- Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else.

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The introduction should "introduce" the manuscript. The reviewer should be presented with sufficient background information to be capable of comprehending and calculating the purpose of your study without having to refer to other works. The basis for the study should be offered. Give the most important references, but avoid making a comprehensive appraisal of the topic. Describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will give no attention to your results. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here.



The following approach can create a valuable beginning:

- Explain the value (significance) of the study.
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Approach:

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This part is supposed to be the easiest to carve if you have good skills. A soundly written procedures segment allows a capable scientist to replicate your results. Present precise information about your supplies. The suppliers and clarity of reagents can be helpful bits of information. Present methods in sequential order, but linked methodologies can be grouped as a segment. Be concise when relating the protocols. Attempt to give the least amount of information that would permit another capable scientist to replicate your outcome, but be cautious that vital information is integrated. The use of subheadings is suggested and ought to be synchronized with the results section.

When a technique is used that has been well-described in another section, mention the specific item describing the way, but draw the basic principle while stating the situation. The purpose is to show all particular resources and broad procedures so that another person may use some or all of the methods in one more study or referee the scientific value of your work. It is not to be a step-by-step report of the whole thing you did, nor is a methods section a set of orders.

Materials:

Materials may be reported in part of a section or else they may be recognized along with your measures.

Methods:

- Report the method and not the particulars of each process that engaged the same methodology.
- Describe the method entirely.
- To be succinct, present methods under headings dedicated to specific dealings or groups of measures.
- Simplify—detail how procedures were completed, not how they were performed on a particular day.
- If well-known procedures were used, account for the procedure by name, possibly with a reference, and that's all.

Approach:

It is embarrassing to use vigorous voice when documenting methods without using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result, when writing up the methods, most authors use third person passive voice.

Use standard style in this and every other part of the paper—avoid familiar lists, and use full sentences.

What to keep away from:

- Resources and methods are not a set of information.
- Skip all descriptive information and surroundings—save it for the argument.
- Leave out information that is immaterial to a third party.



Results:

The principle of a results segment is to present and demonstrate your conclusion. Create this part as entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

Content:

- Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
- In the manuscript, explain each of your consequences, and point the reader to remarks that are most appropriate.
- Present a background, such as by describing the question that was addressed by creation of an exacting study.
- Explain results of control experiments and give remarks that are not accessible in a prescribed figure or table, if appropriate.
- Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or manuscript.

What to stay away from:

- Do not discuss or infer your outcome, report surrounding information, or try to explain anything.
- Do not include raw data or intermediate calculations in a research manuscript.
- Do not present similar data more than once.
- A manuscript should complement any figures or tables, not duplicate information.
- Never confuse figures with tables—there is a difference.

Approach:

As always, use past tense when you submit your results, and put the whole thing in a reasonable order.

Put figures and tables, appropriately numbered, in order at the end of the report.

If you desire, you may place your figures and tables properly within the text of your results section.

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If you put figures and tables at the end of some details, make certain that they are visibly distinguished from any attached appendix materials, such as raw facts. Whatever the position, each table must be titled, numbered one after the other, and include a heading. All figures and tables must be divided from the text.

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Position your understanding of the outcome visibly to lead the reviewer through your conclusions, and then finish the paper with a summing up of the implications of the study. The purpose here is to offer an understanding of your results and support all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of results should be fully described.

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Research papers are not acknowledged if the work is imperfect. Draw what conclusions you can based upon the results that you have, and take care of the study as a finished work.

- You may propose future guidelines, such as how an experiment might be personalized to accomplish a new idea.
- Give details of all of your remarks as much as possible, focusing on mechanisms.
- Make a decision as to whether the tentative design sufficiently addressed the theory and whether or not it was correctly restricted. Try to present substitute explanations if they are sensible alternatives.
- One piece of research will not counter an overall question, so maintain the large picture in mind. Where do you go next? The best studies unlock new avenues of study. What questions remain?
- Recommendations for detailed papers will offer supplementary suggestions.

Approach:

When you refer to information, differentiate data generated by your own studies from other available information. Present work done by specific persons (including you) in past tense.

Describe generally acknowledged facts and main beliefs in present tense.

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Topics	Grades		
	A-B	C-D	E-F
Abstract	Clear and concise with appropriate content, Correct format. 200 words or below	Unclear summary and no specific data, Incorrect form Above 200 words	No specific data with ambiguous information Above 250 words
Introduction	Containing all background details with clear goal and appropriate details, flow specification, no grammar and spelling mistake, well organized sentence and paragraph, reference cited	Unclear and confusing data, appropriate format, grammar and spelling errors with unorganized matter	Out of place depth and content, hazy format
Methods and Procedures	Clear and to the point with well arranged paragraph, precision and accuracy of facts and figures, well organized subheads	Difficult to comprehend with embarrassed text, too much explanation but completed	Incorrect and unorganized structure with hazy meaning
Result	Well organized, Clear and specific, Correct units with precision, correct data, well structuring of paragraph, no grammar and spelling mistake	Complete and embarrassed text, difficult to comprehend	Irregular format with wrong facts and figures
Discussion	Well organized, meaningful specification, sound conclusion, logical and concise explanation, highly structured paragraph reference cited	Wordy, unclear conclusion, spurious	Conclusion is not cited, unorganized, difficult to comprehend
References	Complete and correct format, well organized	Beside the point, Incomplete	Wrong format and structuring

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