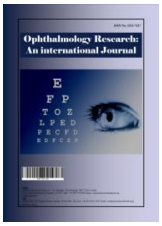

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Comparison of Visual Outcomes between Panretinal Photocoagulation and Panretinal Photocoagulation Plus Intravitreal Bevacizumab in Proliferative Diabetic Retinopathy Patients Treated at Northen Zonal Hospital

Filemon Darabe[1*] and William Makupa[1,2]

[1]Kilimanjaro Christian Medical University College, P.O.Box 2240 Moshi, Tanzania.
[2]Kilimanjaro Christian Medical Centre, P.O.Box 3010 Moshi, Tanzania.

Authors' contributions

This work was carried out in collaboration between both authors. Author FD designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author WM participated during analysis and helped in the production of this final manuscript. Both authors read and approved the final manuscript.

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ABSTRACT

Introduction: Diabetic retinopathy is one of the rigorous microvascular complications of diabetes mellitus is the significant cause of visual impairment and consequently blindness affecting about 36% of the diabetic population. Diabetic macular edema (DME) and proliferative diabetic retinopathy (PDR) are two prime manifestations of DR that are responsible for visual morbidity. The basis of the treatment in PDR is Laser photocoagulation as accomplished by Diabetic retinopathy treatment study (DRS) and early treatment diabetic retinopathy study (ETDRS) for the last two decades. The dawn of intravitreal anti-VEGF agents has revolutionized the management of diabetic eye disease for more than the last decade. The aim of the study is to compare the visual outcomes of diabetic retinopathy patients between pan-retinal photocoagulation and pan-retinal photocoagulation plus intravitreal Bevacizumab.

**Corresponding author: E-mail: jphylemon7@gmail.com;*

Methodology: A hospital-based cross-section study using medical record information for all DR patients treated by PRP and IVB at the KCMC eye. Data were analyzed using SPSS version 20.
Results: A number of 204 patients were included in the study. The mean age was 59.26 (SD=9.6) years; 75.4% were male. Most of the patients 71.1% are from Arusha and Kilimanjaro. Among all, 51% had PRP alone and the duration of Diabetes was 5-10 years in the majority. The mean VA for PRP alone was 0.89 (SD=0.89) before treatment while it was 1 (SD=0.99) in PRP plus Bevacizumab. At 3 months after treatment VA for PRP alone was 0.947 (SD=0.93) and 0.96 (SD=1.01) for PRP plus Bevacizumab. The mean difference was not statistically significant. VA improved by 49% and it deteriorated by 27.7%. The majority had early proliferated DR 49.7%, 42.8% high risk proliferated DR and advanced proliferated DR was 7.5%. The complications were found in 5.6% and they included: vitreous hemorrhage (4.6%) and retinal detachment (1%) in PRP plus Bevacizumab and none in PRP alone.
Conclusion: With respect to this study there is no significant difference in visual outcome for PRP alone and PRP plus injection Bevacizumab, though PRP plus Bevacizumab in treatment of DR had better visual outcome over PRP alone. PRP plus injection Bevacizumab is associated with a higher and early rate of regression of active NVs than PRP alone in patients with PDR. Further studies will be needed to determine whether IVB plus PRP is a satisfactory treatment for the prevention of vision-threatening complications such as vitreous hemorrhage and tractional retinal detachment.

Keywords: Bevacizumab; PRP; diabetic retinopathy; diabetic macula edema.

1. INTRODUCTION

Diabetes mellitus is the main danger of community health concern internationally according to the survey done in 2015. Diabetes mellitus (DM) is a metabolic problem that is described by hyperglycemia because of damaged insulin creation or deficient insulin activity or both. Diabetes mellitus is an important cause of visual impairment and hence loss of sight in the course of causing Diabetic retinopathy (DR) is one of the widespread and rigorous complications [1].

387 million people aged ranging from 20 to 79 years globally are suffering from diabetic Mellitus, making the prevalence of 8.3%. In Sub Saharan Africa, 14 million citizens aged between 20 to 79 years are suffering from diabetic Mellitus, making the prevalence of 3.2% while In Tanzania the likely prevalence of diabetic Mellitus is about 9.1% [2]. It was also expected by the International Diabetic Federation (IDF), that in Sub-Saharan Africa the number of adults aged between 20 to 79 years with diabetic Mellitus will raise from 14millions in 2015 arrive at 34.2 million by end of 2040 owing to inhabitants growth, aging, and raise in obesity and inactive lifestyle in these regions [2].

Diabetic Mellitus patients are at risk of several complications such as diabetic retinopathy. Diabetic retinopathy causes blood-retinal barrier breakdown, leading to augmented permeability and leakage from retinal capillaries. Fluid accumulates inside the retinal layers, ensuing in a thickened macula. Diabetic macular edema (DME) is the mainly widespread cause of vision loss in diabetic patients, with a prevalence that ranges from 19% to 65% [3]. 90% of diabetic patients will have several types of retinopathy twenty-five years following diagnosis.

Diabetic retinopathy is liable for about 2.6% of loss of sight and 1.9% of moderate to severe visual impairment worldwide [4]. Bulks of diabetic patients with diabetic retinopathy are asymptomatic and are not conscious if diabetic Mellitus is a danger of visual loss. This creates the disease to grow towards the higher stage which further from treatment resulting in blindness [5,6].

There several treatment options of diabetic retinopathy depending on its grade. Pan-retinal Photocoagulation (PRP) is indicated in Proliferative diabetic retinopathy. It reduces the incidence of severe visual loss by 50%. It induces involution of new vessels [7].

Intravitreal injection of Triamcinolone (in pseudophakic patients only) or anti-VEGF, in particular, have shown to be an alternative to focal or grid laser in the treatment of CSME involving the center of the macula, as these drugs have shown to effective in reducing macular edema and anti-VEGF prevent retinal neovascularization. Also, studies have shown that the combination of laser therapy (focal or grid laser) and intravitreal injection of triamcinolone or anti-VEGF to be very effective in the treatment of CSME than laser therapy alone

[8–10]. The currently available anti-VEGF are Ranibizumab, Bevacizumab (Avastin), and Pegaptanib. Pars plana vitrectomy is indicated in refractory clinically significant macular edema, harsh persistent vitreous hemorrhage, progressive traction RD, rhegmatogenous RD and pre macular sub hyaloid hemorrhage [11].

Photocoagulation was formerly performed by Meyer-Schwickerathand at rest remains the major useful treatment for proliferative diabetic retinopathy. The advantageous effects of PRP for diabetic retinopathy and its efficiency in decreasing the incidence of blindness were reputed almost 20 years ago by a multicentric study, the Diabetic Retinopathy Study (DRS). Both DRS and the ETDRS provided information to institute the guidelines for finding effective treatment of proliferative diabetic retinopathy (PDR) and diabetic macular edema. While the DRS findings established that PRP reduces the risk of severe visual hammering in patients with high-risk PDR by 50-60%, ETDRS reported the efficiency of using photocoagulation to treat diabetic macular edema and suggested that documented pan-retinal photocoagulation should be initiated early to be most effective in the management of PDR. [14].

There is limited information in our setting on visual outcome in proliferative diabetic retinopathy between patients who underwent pan-retinal photocoagulation and pan-retinal photocoagulation plus intravitreal bevacizumab.

2. MATERIALS AND METHODS

2.1 Study Design and Area

This was an analytical cross-sectional study conducted at KCMC Eye Clinic. KCMC is located in the foothills of the snow-capped, Mount Kilimanjaro, Tanzania. It was opened in March 1971 by the Good Samaritan Foundation, who planned and raised large funds to build and equip it. KCMC is a referral hospital for over 15 million people in Northern Tanzania.

2.2 Study Population

All diabetic patients attended the eye clinic at KCMC hospital

2.2.1 Inclusion criteria

All diabetic patients above 30 years diagnosed as diabetic retinopathy on the treatment of either on PRP or PRP plus injection Bevacizumab at KCMC eye clinic.

2.2.2 Exclusion criteria

All diabetic patients meeting the above criteria but have incomplete medical records and lost to follow-up

2.3 Sample Size

Used sample size (N) was calculated from the following formula;

$$N = [(1/q_1 + 1/q_2)\, S^2\, (Z_\alpha + Z_\beta)^2] / E^2$$

Where,

Z_α = 1.96 for 95%CI, Z_β = 0.84 when power of the study is 80%, q_1 = proportion of subjects in group 1, q_2 = proportion of subjects in group 2, S = standard deviation and E = expected effect size. A total of 102 patients were included

2.4 Sampling Method

Purposive sampling method was used.

2.5 Variables

2.5.1 Independent variables

Were age, sex, education level, ethnicity, residence, systolic BP, duration of diabetes mellitus, diabetic Mellitus treatment type, random blood sugar.

2.5.2 Dependent variables

Visual acuity and grades of diabetic retinopathy,

2.6 Data Collection Technique

After the KCMUCo research ethics committee has given clearance to continue with the research, patients' medical files of those on PRP or PRP plus injection Bevacizumab treatments were obtained from the KCMC eye department.

We reviewed the patient's medical charts, demographic information (age, sex, and dwelling and education level), and duration of diabetes, duration of treatment, RBG, HbA1c, height, weight, and VA. Patient ware categorized as living in urban or rural depending on dwelling information. Those coming from town areas were categorized as living in an urban area; others categorized as living in a rural area.

All identified diabetic retinopathy patients who are on PRP and injection Bevacizumab were recorded in paper form then entered into the database.

2.7 Data Analysis Plan

Data analysis was done by SPSS version 20. The distinctiveness of the study population was summarized using means, median, Standard Deviation, and frequency with proportion for categorical variables. Differences in mean values were compared using the t-test and proportions were compared with the chi-squared test. An independent sample t-test was used to compare VA in the group of PRP alone and the group of PRP plus Bevacizumab. A p-value of <0.05 was considered to indicate statistical significance.

3. RESULTS

3.1 Visual Acuity Outcome

This study involved proliferative diabetic retinopathy patients who either had PRP alone or PRP plus Bevacizumab. In the case where both eyes were treated, we selected the right eye. All patients were treated between 2016 and 2018. Most of the patients were aged between 50 and 69 years (75.4%). Males were predominant (59.8%) and most of the patients were Chagga by tribe (44.6%). The majority had primary education (46%). Most of the patients were coming from Kilimanjaro and Arusha (71.1%) (Table 1).

Our patients had systolic and diastolic blood pressure above the normal range. Mean systolic blood pressure was 154.7 mmHg (SD=27.9 mmHg) while the mean diastolic pressure was 85.2 mmHg (SD=12.9 mmHg). Half of the patients are known as diabetic for 5 to 10 years. Among 206 patients, 51% had PRP alone (Table 2).

There was no statistically significant association between mode of treatment and gender (p=0.61), age (p=0.57), duration of diabetes (p=0.38), residence (p=0.79) and education level (p=0.06) (Table 3).

Table 1. Socio-demographic characteristics of the study participants (N=204)

Variable	Frequency	Percentage
Age in years (mean=59.25±9.6)		
<50	24	11.7
50-59	78	38.2
60-69	76	37.2
70-79	24	11.8
≥80	2	1
Sex		
Male	122	59.8
Female	82	40.2
Tribe		
Chagga	90	44.6
Massai	18	8.9
Pare	23	11.4
Meru	6	3.0
Other	67	32.2
Education level (N=189)		
Primary	87	46.0
Secondary	46	24.3
College/university	56	29.6
Residence		
Kilimanjaro	94	46.1
Arusha	51	25.0
Manyara	7	3.4
Tanga	13	6.4
Other	39	19.1

Table 2. Clinical characteristics of the study participants (N=204)

Variable	Frequency	Percentage
Systolic BP (N=198) (mmHg) (Mean=154.7; SD=27.9)		
< 120	12	6.1
120-139	47	23.7
140-159	57	28.8
≥160	82	41.4
Diastolic BP(N=198) (mmHg) (Mean=85.2; SD=12.9)		
<80	70	35.4
80-89	55	27.8
90-99	49	24.7
≥100	24	12.1
Duration of DM (N=184) (Mean=10.1; SD=5.9)		
<5	19	10.3
5-10	95	51.6
11-15	40	21.7
16-20	15	8.2
>20	15	8.2
Treated eye		
OD	147	72.1
OS	57	27.9
Mode of treatment		
PRP alone	104	51.0
PRP + Bevacizumab	100	49.0
VA OD before treatment(N=199)		
6/18 and better	95	47.7
Less than 6/18 and better than 6/60	31	15.6
6/60-cf3m	23	11.6
Less than cf3m	50	25.1
VA OS before treatment(N=202)		
6/18 and better	89	44.1
<6/18 and >6/60	46	22.8
6/60-cf3m	26	12.9
Less than cf3m	41	20.3

Table 3. Association between socio-demographic characteristics and mode of treatment

Variables	PRP	PRP+ Bevacizumab	OR (95%CI)	p-value
	n (%)	n (%)		
Gender				
Male	64 (52.5)	58 (47.5)	1.16 (0.66-2.03)	0.61
Female	40 (48.8)	42 (51.2)		
Age (years)				
0-59	50 (49.0)	52 (51.0)	0.85 (0.49-1.48)	0.57
60-100	54 (52.9)	48 (47.1)		
Duration of DM (years)				
0-10	55(48.2)	59 (51.8)	0.78 (0.45-1.36)	0.38
>10	49 (54.4)	41 (45.6)		
Residence				
Kilimanjaro	47 (50)	47 (50)	0.93 (0.54-1.61)	0.79
Others	57 (51.8)	53 (48.2)		
Education level(N=189)				
College/University	25 (44.6)	31 (55.4)	0.55 (0.29-1.03)	0.06
Others	79 (59.4)	54 (40.6)		

Table 4. VA before and after treatment in the treated eye and the other eye

VA	Frequency	Percentage
Treated eye before treatment(N=200)		
6/18 and better	89	44.5
<6/18 and >6/60	39	19.5
6/60-cf3m	25	12.5
Less than cf3m	47	23.5
Another eye before treatment(N=198)		
6/18 and better	95	47.3
<6/18 and >6/60	37	18.4
6/60-cf3m	24	11.9
Less than cf3m	45	22.4
Treated eye after treatment(N=200)		
6/18 and better	87	43.5
<6/18 and >6/60	43	21.5
6/60-cf3m	31	15.5
Less than cf3m	39	19.5
Another eye after treatment(N=200)		
6/18 and better	96	48.0
<6/18 and >6/60	30	15.0
6/60-cf3m	28	14.0
Less than cf3m	46	23.0

Table 5. Visual acuity of the treated eye with PRP compared to PRP plus Bevacizumab after 3 months of treatment (N=200)

Variables	Visual acuity of a treated eye after treatment				χ^2	P-value
Mode of treatment	≤6/18	<6/18- >6/60	6/60-cf3m	<cf3m		
	n (%)	n (%)	n (%)	n (%)		
PRP	44 (43.1)	24 (23.5)	10 (9.8)	24 (23.5)	6.5	0.09
PRP + Bevacizumab	43 (43.9)	19 (19.4)	21(21.4)	15 (15.3)		

Table 6. Comparison of pre-treatment VA and VA at 3 months between the two treatment modalities in the treated eye

Variables		Mean VA ±SD	Mean difference	95% CI	p-value
Timing	Treatment modality				
Baseline	PRP	0.89 ± 0.87	-0.11	-0.37-0.15	0.41
	PRP+Bevacizumab	1.00 ± 0.99			
At 3 months	PRP	0.947 ± 0.93	-.013	-0.28-0.26	0.92
	PRP+Bevacizumab	0.96 ± 1.01			

The mean VA in PRP alone was 0.89 (SD=0.87) before treatment while it was 1 (SD=0.99) in PRP + Bevacizumab. At 3 months after treatment, the mean VA was 0.947 (SD=0.93) and 0.96 (SD=1.01) in PRP alone and PRP plus Bevacizumab injection respectively. The mean difference was not statistically significant (Table 6).

Only 49% had their visual acuity improved after treatment. The visual acuity deteriorated in 27.7% while it improved in 23.3% (Table 7).

Visual acuity improved more in the group which had PRP+ Bevacizumab (53.1%) compared to the group of PRP alone (45.2%), however, the difference was not statistically significant (Table 8). The majority of patients had early proliferation in the treated eye (49.7%), 42.8% had high-risk proliferation while 7.5% had advanced proliferation in the treated eye (Table 9).

There was a statistically significant association between the severity of diabetic retinopathy and the mode of treatment, p<0.001. Most of the patients with high-risk diabetic retinopathy and

advanced retinopathy were treated with PRP plus Bevacizumab (42.8%) (Table 10). Most of the patients did not have complications related to treatment 94.4% however, 4.6% had a vitreous hemorrhage and 1% had retinal detachment (Table 11). Few patients in both PRP and PRP plus Bevacizumab got complications. In PRP group 4 (44.4%) had a vitreous hemorrhage, no case of retinal detachment observed. In PRP plus Bevacizumab, 5 (55.6%) got vitreous hemorrhage and 2 patients had retinal detachment (Table 12).

Table 7. Change in visual acuity after treatment (N=202)

Visual acuity	Frequency	Percentage
Deteriorated	56	27.7
Same	47	23.3
Improved	99	49.0
Total	202	100.0

Table 8. Association between visual acuity improvement and mode of treatment (N=202)

Variables	VA after treatment		χ^2	p-value
	Not improved	Improved		
	n (%)	n (%)		
Mode of treatment				
PRP alone	57(54.8)	47(45.2)	1.25	0.26
PRP+ Bevacizumab	46(46.9)	52(53.1)		

Table 9. Severity of Diabetic retinopathy among treated patients (N=201)

Severity	Frequency	Percentage
Early proliferative	100	49.7
High risk proliferative	86	42.8
Advanced proliferative	15	7.5
Total	201	100

Table 10. Association between severity of retinopathy and mode of treatment

Variables	PRP	PRP+ Bevacizumab	χ^2	p-value
	n (%)	n(%)		
Severity of PDR				
Early proliferative	89 (89.0)	11 (11.0)	128.04	<0.001
High risk proliferative	11 (12.8)	75 (87.2)		
Advanced	3 (20.0)	12 (80.0)		
Not staged	0 (0.0)	2 (100)		

Table 11. Complications of PRP and PRP plus Bevacizumab

Complications	Frequency	Percentage
None	185	94.4
VH	9	4.6
RD	2	1.0
Total	196	100

Table 12. Association between the mode of treatment and complications

Variables	Complications			χ^2	p-value
	None	Vitreous hemorrhage	Retina detachment		
Mode of treatment	n (%)	n (%)	n (%)		
PRP	99 (53.5)	4 (44.4)	0 (0.0)	2.19	0.39
PRP+ Bevacizumab	86 (46.5)	5 (55.6)	2 (100)		

4. DISCUSSION

Our study shows that 49% of the participants with diabetic retinopathy treated with PRP alone and PRP plus injection Bevacizumab had improved in their vision. This is because most of the patients were screened and started treatment on time. Those with poor improvement have a long duration of DM.

Among treated patients, males were 59.8% these might be due to DM to be more common than females, and most of the patients were Chagga 44.6% by the tribe because KCMC hospital is located at Kilimanjaro region where Chagga are found and Arusha region have Chagga too. Seventy-one point one percent of the patients were coming from Kilimanjaro and Arusha due to the location of KCMC hospital. Most of the patients have a 46.0% primary education level because most of them were coming out of town and nature of the work.

The mean systolic and diastolic blood pressure are 154.7 mmHg (SD=27.9 mmHg) and 85.2 mmHg (SD=12.9 mmHg) meaning some of the patients also are hypertension with a different lifestyle. Half of the patients are diabetic for 5 to 10 years this is because most of the complications of DM started from 5 years and most of the patients came to the hospital with complications. Fifty-one percent of the patients underwent PRP alone, early proliferative diabetes retinopathy 49.7%.

The visual acuity deteriorated in 27.7% while it stayed the same in 23.3%. In our study, there was no significant vision improvement 3 months after treatment. We only recorded the visual acuity before treatment and 3 months after treatment.

This is different from the study done at University of California on January 2015 that shows 85% underwent laser PRP plus an injection of Bevacizumab, the mean visual acuity improved from 20/214 at baseline to 20/46 at 1-month, 20/48 at 3-month, and 20/59 at the 6-month follow-up, and 53% showed an improvement in VA of more than 3 lines on the Snellen acuity. Therefore no patient had a loss of vision greater than one line of Snellen acuity at the last visit [15].

In prospective case series study among 20 eyes with high-risk PDR, the visual acuity improved from 1.03 to 0.38 at three months post-treatment with IVB plus PRP [16]. In a study done by Dr. Once in patients with mild to high-risk diabetic retinopathy. 46 eyes of 23 patients have been treated with injection Bevacizumab and PRP 5 to 7 days after treatment compared to the control group (Oncel Murat 2008).

A study was done, 27 eyes for PRP plus injection Bevacizumab, and 47 eyes for PRP alone were evaluated and resulted in no statistically different is visual acuity with a p-value of 0.003. (Jongjae Oh 2014). In a study done by Mushtaq Ahmad in 2012, 54 eyes we randomly evaluated and the mean visual acuity in PRP alone group was worsening significantly from 0.30±0.07 to 0.40±0.04 at 30 days and mean at 0.40±0.04 at 90 days. However, in PRP plus injection group the visual acuity was improved at 4 weeks by 0.30±0.05 to 0.1±0.02 and mean of 0.1±0.02 at 12 weeks [17].

A retrospective study done by Yong Woon shin 2009, patients with high risk proliferative Diabetic retinopathy was divided into PRP alone group and PRP plus injection Bevacizumab. After the study, there were no statically different in visual acuity in either group with p=0.916 and p=0.888 respectively [18].

Our study shows the majority of patients had early proliferation DR in the treated eye (49.7%), 42.8% had high-risk proliferation while 7.5 % had advanced proliferation in the treated eye.

This shows that most of the patients with diabetes Mellitus are coming from Kilimanjaro and Arusha where KDP and ADP screening programs for DR are based; all diabetic patients are screened for diabetic retinopathy and those with proliferative retinopathy or referable maculopathy are called to attend the clinic at KCMC eye clinic.

However most of the patients with high risk proliferative and advance proliferative DR they come in the late stage of the disease. Fifty-one point one percept of the patient had 5-10 years with DM without being screened for DR.

The differences with the other studies can be explained by the sample size, duration of DM, and early attendance to the diabetic eye clinic.

With respects to the severity of diabetic retinopathy, there has been elevated prevalence of Diabetic retinopathy and some of the severities especially the moderate-severe pre-

proliferative diabetic retinopathy and proliferative diabetic retinopathy in developing countries compared to developed countries were established by an extensive review published in 2012 using individual-level data from 35 population-based studies on 22896 diabetic patients [19].

Our study shows the majority of patients had early proliferation DR in the treated eye (49.7%), 42.8% had high-risk proliferation while 7.5 % had advanced proliferation in the treated eye. This shows that most of the patients with diabetes Mellitus are coming from Kilimanjaro and Arusha where KDP and ADP screening programs for DR are based; all diabetic patients are screened for diabetic retinopathy and those with proliferative retinopathy or referable maculopathy are called to attend the clinic at KCMC eye clinic.

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With respects to the severity of diabetic retinopathy, there has been elevated prevalence of Diabetic retinopathy and some of the severities especially the moderate-severe pre-proliferative diabetic retinopathy and proliferative diabetic retinopathy in developing countries compared to developed countries were established by an extensive review published in 2012 using individual-level data from 35 population-based studies on 22896 diabetic patients [19].

5. CONCLUSION

The treatment of DR depends on severity. With respect to this study, there is no significant difference in visual outcome for PRP alone and PRP plus injection Bevacizumab, though PRP plus Bevacizumab in treatment of DR has better visual outcome over PRP alone. Injection Bevacizumab and PRP is a safe and effective adjunctive treatment to PRP in the short term. PRP plus injection Bevacizumab is associated with a higher and early rate of regression of active NVs than PRP alone in patients with PDR. PRP plus IVB treated eyes also showed better visual outcome compared to PRP only eyes in PDR; further studies will be needed to determine whether IVB plus PRP is a satisfactory treatment for the prevention of vision-threatening complications such as vitreous hemorrhage and tractional retinal detachment.

6. STUDY LIMITATIONS

In this study, some data such as staging of retinopathy and complications were missing in some of the patients' files. Moreover, we only looked at the outcome and complications after 3 months. Some complications will happen after months or even years; it is possible that the rate of complications was underestimated in our study.

CONSENT

Written and informed concert as per international standards has been obtained from the appropriate authority.

ETHICAL APPROVAL

Ethical approval was obtained from the Kilimanjaro Christian Medical University College research ethical committee.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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