

Functional Outcomes of patellar fracture After Operative Treatment and Its Associated Factors at Addis Ababa Burn, Emergency and Trauma Hospital, Ethiopia

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Abstract

Background: Although patellar fracture is relatively rare fracture, accounting about 1% of all fractures, it result in significant disability due to loss of extensor mechanism of knee. This study aimed to assess the functional outcome of patients with patellar fractures who were treated surgically and its associated factors at Addis Ababa Burn, Emergency and Trauma (AaBET) hospital, Ethiopia.

Objectives: This study aimed to assess the functional outcome of patients with patellar fractures who were treated surgically and its associated factors at Addis Ababa Burn, Emergency and Trauma (AaBET) hospital, Ethiopia.

Methods: A cross-sectional study was used. All patients who sustained patellar fracture and operated at AaBET hospital was included to the study. The data was entered using Epi Info and exported to and analyzed using SPSS version 26. Both bivariate and multivariable logistic regression analyses were performed. Adjusted odds ratio (AOR) with 95% confidence interval (CI) and p-value <0.05 were used to declare statistical significance.

Results: Among 145 study participants, 60% of them were male. Fall dawn injury (42.75%) was the main mechanism of injury in study participants. Most of the fractures in the study participants were closed fractures (77.9%). Tension band wiring (64.8%) followed by tension band wiring with cerclage (22%) were the two most commonly performed surgical interventions. Majority of the study participants had attended formal knee physiotherapy (72.4%) and implant was removed in 56% of the study participants. Being male and young age were associated with good functional outcome. The mean of functional outcome for each Knee Injury and Osteoarthritis Outcome Score (KOOS) subscales were less than the mean of young standard population; the difference was statistically significant for all components.

Conclusion: Overall, patient reported functional outcome was poor in patients with patellar fracture who treated surgically. Sex, age, and whether the implant was removed or not were significantly associated with patient reported functional outcome of patellar fracture.

Keywords: Patella fracture, Functional outcome, Knee Injury and Osteoarthritis Outcome Score (KOOS), Addis Ababa, Ethiopia

Introduction

Patella is the largest, grossly flat and triangular sesamoid bone located anterior to knee joint (1). It is one of the components of extensor mechanism of the knee, located within the tendon of quadriceps femoris. The other components of extensor mechanism of the knee includes quadriceps muscle complex, quadriceps tendon, patellar retinaculum, patellar tendon and its insertion onto the tibial tubercle (1,2). It is highly vascularized with abundant anastomotic network (1) and it is innervated by two nerves that reach the patella from vastus lateralis and vastus medialis (3).

The primary biomechanical function of the patella is to improve quadriceps efficiency by increasing the lever arm of the extensor mechanism (1). So it allows an individual to overcome gravity and important for ambulation, standing from a seated position and walking up and down stairs (2,4).

Patellar fractures constitute approximately 1% of all fractures (5,6). There is no universally accepted treatment approach towards this relatively common injury. Displacement greater than 3 millimeters and articular step-off greater than 2 millimeters with disruption of extensor mechanism are generally accepted indications for surgery. Numerous treatment methods, including partial excision, tension band, modified tension band, osteosynthesis with plates and screws, suture repair, cerclage wiring, percutaneous open reduction and internal fixation, total patellectomy, arthroscopic-assisted open reduction and internal fixation, and external fixation, have been used for patellar fractures (6–8).

Previous studies done elsewhere to assess an outcome of operatively treated patellar fractures showed that functional outcome is not good (5,9,10). Previous researchers found patients who are surgically treated for patellar fractures had relatively poor physical health outcomes as measured by the short form 36 (SF-36) questionnaires and knee injury and osteoarthritis outcome score (KOOS) (5,11). Other authors also analyzed objective outcome of patients with patellar fracture treated with surgical intervention as compared to contralateral limb or normal population and found disappointing results (5). Others also studied potential factors contributing to poor outcome in operatively treated patellar fractures and found fracture severity, comorbidity, smoking and extensive tension band construct are strongly associated with poor outcome (12–14).

There are only few literatures reporting on the follow-up of these debilitating fractures, especially following modern operative techniques. Majority of assessment of outcome of patellar fracture are focused on comparison between different treatment modalities and fracture patterns. Most of the authors did not use the standardized functional assessment tool and the results are inconsistent and difficult to compare. There are few literatures that use validated scoring system like KOOS and Lysholm scores; which found that patients who sustain patella fractures that require operative treatment have persistent major physical sequel (15,16).

Majority of the researchers studying outcome of patellar fracture after surgical fixation compare outcome based on either pattern of fracture or fixation technique they used (3,16–22). Most of the researchers used either non-validated functional scoring instrument or their own functional assessment tools. Their results are usually conflicting and difficult to compare and most of them did not study contributing factors for poor outcome following surgical treatment of patellar fractures. Others use only few numbers of patients and results are weak; it is difficult to make conclusion and use it in clinical practice. Moreover, literatures on outcome analysis following surgical intervention of patellar fractures are scarce in African countries. This study will improve the medical service provided for patients with patellar fracture who are candidate for surgical fixation and help to develop the management protocol.

This study provided data on outcome of patients with patellar fracture who are treated surgically and will help surgeon to advice his/her patients on possible functional outcome after surgery. It had also provided baseline information for other researcher who wants to conduct further study on this area. The finding of this study will contribute to the understanding of outcome of patellar fracture patients treated surgically in our trauma center.

Methods and Materials

Study setting, design, and period

A hospital-based cross-sectional study design was conducted in Orthopedics and Traumatology department of AaBET Hospital. AaBET hospital is an affiliate of St. Paul's Hospital Millennium Medical College (SPHMMC), one of the largest tertiary hospitals in the country based in the capital city of our Ethiopia, Addis Ababa. It is the first trauma

hospital established in Ethiopia since 2015 with 250-beds and 12 intensive care unit beds; and averagely 20-30,000 patients visit the emergency department annually. It has been giving neurosurgery, orthopedics, trauma, burn, emergency and critical care services since its establishment. It has a total of four operation room (OR) tables and two recovery rooms. The hospital provides both emergency and elective surgical services to the needy patients 24 hours a day (32). The study was conducted over 2 month's period, from first January to twenty eighth February, 2022.

Study population, sample size, and sampling procedures

All patients who were diagnosed with patellar fracture and treated surgically in AaBET hospital's trauma center from first September 2015 to 30 August 2020 were included in the study based on the inclusion criteria of this study. All patients who aged 18 to 80 year were included to the study. Sample size was calculated using single population proportion as follows: since the source population is only 200, which is below 10,000, population correction formula was used to determine adjusted minimum sample size. The calculated minimum sample size was 145. Sample of patients who had treated for patellar fracture from September 2015 to August 2020 were selected using simple random sampling technique from the sampling frame.

Operational definitions and measurements

Functional outcome is the subjective assessment of patients as measured using knee injury and osteoarthritis scoring (KOOS system).

Good Functional outcome is a patient whose average KOOS value is ≥ 70 ; as calculated as average of the five components of KOOS.

Poor Functional outcome is a patient whose average KOOS value is < 70 ; as calculated as average of the five components of KOOS.

Comorbidity is any associated medical illness like Diabetic, Hypertension or major organ failure that could potentially affect the functional outcome of patients.

Physiotherapy refers to the formal physiotherapy provided by trained physiotherapist in health institutions and will not include the home-based physiotherapy.

Data collection method, tool and procedures

Functional outcome of patients with patellar fracture who were operatively treated in AaBET hospital was assessed using knee injury and osteoarthritis outcome scoring (KOOS) (33–36) and some questionnaires were also developed by principal investigator to analyze potential factors affecting outcome at the same time. Knee injury and osteoarthritis outcome score (KOOS) is an outcome measurement instrument, developed to assess patient's opinion about their knee and associated problems. It is important in measuring both short and long-term outcome (23,25,36,37). KOOS had 42 items in 5 separately scored subscales: KOOS pain, KOOS symptoms, function in daily living (KOOS ADL), KOOS sport and recreation and KOOS related Quality of Life (QOL) (33).

KOOS was developed in 1990s to assess the patients' opinion about their knee and associated problem. It was internationally validated to be used in patients with any type of knee injury that could potentially result in Osteoarthritis, Total knee replacement, knee ligament reconstruction, meniscectomy and others. In order to better understand the outcome using this scoring system normative value is developed for different group of population based on their age, gender and occupation (24,25). Technically all the five subscales are scored separately: KOOS pain, KOOS symptoms, KOOS ADL, KOOS sport and recreation, KOOS QOL.

Then, the scores will be transformed to 0-100 scale, with zero representing extreme knee problem and 100 represents no knee problem. Then, average KOOS value was calculated as a mean of all the KOOS components. In this study, the scoring software which is available online was used (34).

For this study, the source of the data were Operation theater logbook, patient chart and patient him/herself. The data will be collected at AaBET Hospital. Two trained general practitioners or junior residents were hired for the purpose of this study under supervision of the principal investigator.

Once the patients who fulfill the inclusion criteria are identified, invited to hospital on working days and data collectors filled the questionnaires. If the patient gives the consent but cannot come to hospital the questionnaires were filled with phone call. Phone call was made every

other day for three days over a week; if not reached with this it was declared inaccessible.

Data processing and analysis plan

After completing data collection, data were checked by the principal investigator for completeness and coded. The coded data were entered in to Epi Info and exported to SPSS version 26 for further analysis. Then, mean, median, standard deviation and proportion were calculated for each KOOS subscales and compared to the normal population. Cross-tabulation and Chi-square test were done to assess the association between the dependent and independent variables. Multivariable logistic regression analysis was carried out to see the relative effects of independent variables on the dependent variable. Odds ratio with 95% confidence interval and p-value of less than 0.05 was used to interpret results.

Results

Demographic characteristics of the patients

A total of 145 participants were selected randomly from all patients with patellar fracture who were treated surgically at AaBET hospital. Majority of the patients (60%) were male. Eight-one (~56%), 24 (29%), and 22 (15.2%) of the patients were less than 40, 40-60, and older than 60 years old, respectively.

Clinical characteristics of patients

Fall dawn injury (FDA) was the main mechanism of injury (42.7%), followed by Road traffic accident (RTA) (27%) and violence (26.2%) Eight-tree patients had right sided patellar fracture and only two patients among the patients had bilateral patellar fracture. Majority of the fracture (77.9%) in the participants were closed fracture. Tension band wiring (TBW) (64.8%) followed by TBW plus cerclage (22%) were the most frequently performed surgical fixation. Physiotherapy was ordered for 105 (72%) patients and implant was removed in more than half (56.5%) of the study participants as shown in Table 1.

As it was shown in the following Table 2, the mean of the five different KOOS subscale components were 63.1, 62.6, 61.1, 60.8, and 56.5 for KOOS pain, KOOS symptom, KOOS ADL, KOOS QOL, and KOOS sport and recreation, respectively (see Table 2 for the details).

Patient reported functional outcome

From 145 study participants, nearly three-fourth (74.5%) reported as they have poor functional outcome taking average KOOS value of 70 as cut off point.

Table 1: Clinical characteristics of patients with patellar fracture treated surgically at Addis Ababa Burn, Emergency and Trauma Hospital, Ethiopia, May 2022 (n = 145).

Variable	Category	Frequency (N)	Percentage (%)
Time from injury to presentation to hospital	≤ One day	97	66.9
	One day to one week	37	25.5
	≥ one week	11	7.6
Time from Injury to surgery	≤ One day	46	31.7
	One day to one week	66	45.5
	≥ One week	33	22.8
Mechanism of injury	Fall down	62	42.8
	Road traffic accident	40	27.6
	Violence	38	26.2
	Bullet injury	2	1.4
	Other	3	2.1
Side of fracture	Right	83	57.2
	Left	60	41.4
	Bilateral	2	1.4
Pattern of fracture	Simple	99	68.3
	Complex	46	31.7
Type of patellar fracture	Closed	113	77.9
	Gustillo Anderson type I	21	14.5
	Gustillo Anderson type II	9	6.2
	Gustillo Anderson type IIIA	2	1.4
Type of surgical fixation	TBW	94	64.8
	Cerclage	10	6.9
	TBW + cerclage	32	22.1
	TBW + screw	8	5.5
	Patellectomy	1	0.7
Physiotherapy	Done	105	72.4
	Not done	40	27.6
Status of the implant	Removed	82	56.6
	Not removed	63	43.4

Table 2: Descriptive statistics of the five Knee injury and osteoarthritis outcome score subscales of patients at Addis Ababa Burn, Emergency and Trauma Hospital, Ethiopia, May 2022 (n = 145).

	KOOS pain	KOOS symptom	KOOS ADL	KOOS QOL	KOOS sport and recreation
Mean	63.1	62.7	61.1	60.8	56.5
Median	64.0	64.0	60.0	63.0	60.0
Mode	56.4	71.0	59.0	69.0	60.0
SD	15.8	17.3	13.7	17.9	17.9
Range	78.0	79.0	58.0	75.0	75.0
Minimum	14.0	21.0	29.0	19.0	15.0
Maximum	92.0	100.0	87.0	94.0	90.0

SD: Standard deviation

Factors affecting patient reported functional outcome

Among the variables studied; age, sex, and whether the implant was removed or not were found to have statistically significant association with patient reported functional outcome in patients operatively treated for patellar fractures at the hospital. On Chi-square test, being male was found to have association with good functional outcome (97.6% confidence interval, $X^2 = 5.086$, Phi/Cramer's $V = 0.187$). Age was found

to have negative association with function in operatively treated patients with patellar fracture ($p = 0.001$, $X^2 = 14.924$ Phi/Cramer's $V = 0.321$). Those patients for whom the implant was removed were found to have good patient reported functional outcome compared to those for whom the implant was not removed yet (confidence interval = 100%, $X^2 = 21.536$, Phi/Cramer's $V = 0.385$). See details in Table 3.

Comparing the mean and multiple logistic regression

One sample t-test was used to compare the mean of the five KOOS components of the study participants to the mean of the standard young population and it was found there was statistically significant difference between the two means. P-value is less than 0.05 for all five

components of the KOOS showing significant difference between the mean of the study population and the standard population (Table 4).

In order to see the relative effect of the independent variables on the functional outcome of the operatively treated patients with patellar fracture, multiple logistic regression analysis was performed and odd ratio was calculated. The overall regression model was significant, p -value <0.001 , $X^2 = 38.114$, $R^2 = 0.231-0.340$. The studied variables were responsible for about 23.1%-34% of the outcome. Whether the implant was removed or not more importantly determines the functional outcome of patients with patellar fracture among the study participants compared to other study variables (Table 5).

Table 3: Summary of the association between independent variables and patient-reported functional outcome of patellar fracture at Addis Ababa Burn, Emergency and Trauma Hospital, Ethiopia, May 2022 (n = 145).

Independent Variable		Functional outcome				Chi-square test			Strength of correlation	
		Good		Bad		Value	df	Sign(2-sided)	Phi/Cramer's V	p-value
		Count	%	Count	%					
Sex	Male	28	75.7	59	54.6	5.086	1	0.024	0.187	0.024
	Female	9	24.3	49	45.4					
Age in years	≤40yrs	30	81.1	51	47.2	14.924	2	0.001	0.321	0.001
	40-60yrs	7	18.9	35	32.4					
	≥60yrs	0	0	22	20.4					
Time from injury to presentation to hospital	≤1day	26	70.3	71	65.7	.424	2	0.809	0.054	0.809
	1day-1week	9	24.3	28	25.9					
	≥1week	2	5.4	9	8.3					
Time from injury to surgery	≤1day	16	43.2	30	27.8	3.282	2	0.194	0.150	0.194
	1day-1week	13	35.1	53	49.1					
	≥1week	8	21.6	25	23.1					
Mechanism of injury	RTA	14	37.4	26	24.1	3.926	4	0.416	0.165	0.416
	Violence	10	27	28	25.9					
	FDA	12	32.4	50	46.3					
	Bullet injury	0	0.0	2	1.9					
	Other	1	2.7	2	1.9					
Side of fracture	Right	20	54.1	83	57.2	1.024	2	0.599	0.084	0.599
	Left	17	45.9	60	41.4					
	Bilateral	0	0	2	1.4					
Pattern of fracture	Simple	29	78.4	70	64.8	2.341	1	0.126	0.127	0.126
	complex	8	21.6	28	35.2					
Type of patellar #	Closed	32	86.5	81	75	2.597	3	0.458	0.134	0.458
	G-A type I	4	10.8	17	15.7					
	G-A type II	1	2.7	8	7.4					
	G-A type IIIA	0	0	2	1.9					
Type of surgical fixation	TBW	28	75.7	66	61.1	4.862	4	0.302	0.183	0.302
	Circlage	2	5.4	8	7.4					
	TBW + Circlage	4	10.8	28	25.9					
	TBW + screw	3	8.1	5	4.6					
	Patellectomy	0	0	1	0.9					
Physiotherapy	Done	28	75.7	77	71.3	.265	1	0.607	0.043	0.607
	Not done	9	24.3	31	28.7					
Status of the Implant	Removed	33	89.2	49	45.4	21.536	1	0.000	0.385	0.000
	Not removed	4	10.8	59	54.6					

Table 4: Comparison of the mean of the five KOOS subscales of patients at Addis Ababa Burn, Emergency and Trauma Hospital and normal young US population, May 2022 (n = 145).

KOOS subscale	One sample T-test		
	T	Df	Sig. (2-tailed)
KOOS symptom	-20.790	144	0.000
KOOS pain	-26.184	144	0.000
KOOS ADL	-31.987	144	0.000
KOOS sport and recreation	-26.339	144	0.000
KOOS quality of life	-21.900	144	0.000

As shown in Table 5, when adjusted for other variables, those patients for whom the implant was removed had 7 times odd of having good outcome when compared to those who had still implant in situ. Keeping the other variables constant, the odd of having good outcome in male is 1.5 times more than females. Those patients less than 40 years old had 4 times more likely to have good outcome than those greeter than 40 years old (Table 5).

Table 5: Multiple logistic regression analysis showing the relative effect of different independent variables on Functional outcome of operatively treated patients with patellar fractures at Addis Ababa Burn, Emergency and Trauma Hospital, Ethiopia, May 2022 (n = 145).

List of Independent Variable	Functional outcome			
	COR	P-value (95% C.I)	AOR	P-value (95% C.I)
Status of the implant	9.934	3.291-29.982	7.138	2.264-22.513
Sex	2.584	1.114-5.992	1.522	1.584-3.965
Age	4.014	1.861-9.049	2.654	1.977-7.205

AOR: Adjusted odd ratio, COR: Crude odd ratio

Discussions

This study clearly shows that patellar fracture that need surgical intervention usually end up in poor patient reported functional outcome (74.5%). The mean of the study participants was significantly different from the mean of normal young population in all KOOS components (KOOS pain, KOOS symptom, KOOS ADL, KOOS QOL, KOOS sport and recreation). Being female and older age group strongly associated with poor outcome. Statistically, compared to other variables, implant removal significantly associated with good patient reported functional outcome.

The functional outcome of our study was in accordance with functional outcome reported in other literature. The mean of different KOOS subscales were significantly lower than the mean of normal standard population according to a report from Leuven University hospital, Belgium (p-value for different KOOS subscales range from 0.001 to 0.005) (12) and Adams Cowley Shock Trauma Center, Department of Orthopedic Surgery, University of Maryland Medical Center, Baltimore (15). This finding potentially shows that even a properly treated patellar

fracture might result in residual disability and patients are unlikely regain their pre-injury functional level.

This study demonstrates that overall out comes after patellar fractures are not good. In this study the majority of the sample were male (60%), had right side injury (57%), presented with in one day of injury and majority of them were operated with in a week of the injury (77%). This result is comparable to the result of the study done at Adams Cowley Shock Trauma Center, Department of Orthopedic Surgery, University of Maryland Medical Center, Baltimore (5). This could be explained by the fact that patellar fracture is debilitating injury so that the patients tend to come to the healthy facility early after injury. The mean for different KOOS subscales were also comparable to the study done at University of Maryland Medical Center, Baltimore (5); except KOOS for pain subscales which was better at Baltimore (71.7% versus 60.3%) and KOOS for QOL subscales (60.8 versus 49.6%) which was better in this study. This could be explained by the fact that the studies were conducted in different set up, the study participants have different expectation, and different quality of life.

The subcutaneous location of the patella leaves it susceptible to injuries from direct blows and falls. Because of the small amount of pre-patellar soft tissue and the direct contact with the distal femur, the articular cartilage of the contact area is likely damaged even with minimal fracture diastasis. Direct blows to the patella of less magnitude than that required to create a fracture can predictably damage the contacting articular cartilage and lead to the initiation of posttraumatic osteoarthritis (1,5,38). For virtually all activities, the patellofemoral contact stresses exceed those sustained by the tibiofemoral joint and by other major weight bearing joints. These high contact stresses magnify the importance of maintaining articular congruity in patellar fractures to maximize stress distribution. Persistent subjective complaints and decreased extensor strength may be attributed to residual joint incongruity and the resulting increased contact stresses, which lead to premature degenerative changes. However, the articular surface is frequently injured at the time of the injury and this particular damage may lead to osteoarthritis, even with excellent fracture repair. Clearly, the goal in treating patellar fractures is to accurately reduce fracture fragments and minimize additional insults to the articular cartilage.

This study shows significant difference between the mean of the study participants and mean of the reference young adult population in all KOOS subscales. This is comparable to the study done at Leuven University hospital, Belgium from 2005-2014 (12,15). This could imply that patients with patellar fracture were unlikely to regain their pre-injury level of activity. In our study the mean for KOOS sport and recreation (56.5%) was rated least where as in the above referenced study KOOS QOL subscale rated worst (median 62.5%).

In the present study, sex ($p = 0.024$), age ($p = 0.001$) and whether the implant was removed or not ($p < 0.001$) were significantly associated with outcome of this study whereas the study conducted from 2005-2014 in Belgium, Leuven University hospital found severity of patellar fracture (p -value < 0.001) and type of surgical fixation (TBW, p -value = 0.009) to be significantly associated with patient reported functional outcome. In our study, both pattern of fracture and type of surgical fixation had association with patient reported functional outcome; but we found it was not significant statistically. This difference could happen because they removed symptomatic implant in about three forth of their patients. In this study, compared to other variables implant removal was significantly associated with good outcome (p -value < 0.001). Similar study done in Israel, Tel Aviv University from December 2006 to November 2014 found statistically improved VAS pain score and SF-12 physical function after hardware removal (p -value = 0.0022 and $p = 0.0001$, respectively) but no improvement in the lysholm score (p -value = 0.62). Other factors other than Hardware removal could potentially contribute to the functional outcome.

This study was conducted for the first time in Ethiopia. An Internationally validated functional outcome assessment tool, knee injury and osteoarthritis outcome score (KOOS) was used to assess functional outcome of patients with patellar fractures. However, extensive number of factors that could potentially affect the functional outcome of patients with patellar fracture who were treated surgically were not studied. This study had a number of limitations like small sample size, data were collected from single institutions and study participants were followed for only short period of time.

Conclusions

It can be concluded from this study that majority of patients with patellar fracture treated operatively end up in poor functional outcome. When

compared to the normal standard population, patients treated operatively for patellar fracture had significantly decreased mean value in all KOOS subscales. Sex, age, and whether the implant was removed or not were significantly associated with patient reported functional outcome of patellar fracture. Implant removal was the single most important factor associated with improved functional outcome. The odd ratio of patients for whom the implant was removed was seven times more likely to have good functional outcome when compared to those for whom the implant was not yet removed. Therefore, surgeon should advice his or her patients that even a well-executed surgical intervention could end up in poor functional outcome, special emphasis should be given when an elderly got patellar fracture, and the issue of hardware removal should be discussed with the patient preoperatively and should be strongly considered once the fracture is healed. We need to consider implant removal as important as the initial surgical intervention, determine the mean of different KOOS subscales for the normal population in our setup, and patients should be followed for long period of time to see if there is a change over time.

Abbreviations

AaBET: Addis Ababa Burn, Emergency and Trauma

ADL-activity of daily life

AOR: Adjusted Odds Ratio

CI: Confidence Interval

KOOS: Knee Injury and Osteoarthritis Outcome Score

MRN: Medical Record Number

OR: Operation Room

QOL: Quality of Life

SF-12: 12-item Short Form survey

SPHMMC: St. Paul's Hospital Millennium Medical College

VAS: Visual Analogue Scale

Declaration

Ethics approval and consent to participate

Ethical approval and clearance was obtained from the Institutional Review Board (IRB) of St. Paul's Hospital Millennium Medical College. An official letter for cooperation was sent to Addis Ababa Burn, Emergency, and Trauma (AaBET) hospital. Approval for use of patient records was obtained from AaBET hospital medical director. In addition, verbal informed consent was taken for those patients who

could not come to the hospital and written informed consent was obtained from study participants who could come to hospital after they are given information about the purpose of the study. Confidentiality was maintained when handling each case file. The name and chart of a patient were not shared with anyone outside the research team and the information is used for research purpose only. In general, this study was conducted based on the Declaration of Helsinki.

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Consent for publication

Not applicable.

Competing interest

Authors declare that they have no competing interests.

Availability of data and materials

Datasets used and/or analyzed in the current study are available from the corresponding author upon reasonable request.

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Authors' contributions

All authors contributed to the conception, design, and conduct of the study. GR and TD analyzed and interpreted the data, and drafted the manuscript. TGD was involved in proposal development, data analysis, and critical edited the final manuscript. All authors read and approved the final manuscript.

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