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Comparative Study between Flexible Intramedullary Nail and Sub Muscular Plate in Treatment of Unstable diaphyseal Femoral Fracture

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ABSTRACT

Background: Femoral shaft fractures are among the most frequent fractures that necessitate hospitalization. The treatment of juvenile femoral shaft fractures remains controversial, particularly when they are unstable.

Objectives The aim of this study was to compere between the flexible intramedullary nail and the submuscular plate in fixation of pediatric femoral shaft fractures at the age group between 5 and 12 years old with unstable femoral shaft fractures regarding clinical and radiological outcomes. **Patients and Methods** This prospective cohort study was conducted on 30 patients with unstable femoral shaft fractures aged from 5 to 12, between Feb. 2021 and Feb. 2024. They were randomly subdivided into two groups, group 1 (15 patients) treated by Flexible intra-medullary nails (FNs) and group 2 (15 patients) treated by SMPs. The assessment variables were intraoperative C-arm shots, blood loss, time for radiological union, malunion, leg length discrepancy, and Flynn's score.

Results There was no statistically significant difference between the two groups regarding demographic data, C-arm shots, time for union, complications, the LLD, angular deformity, time for union, and Flynn's score. The FNs group had a significantly lower estimated blood loss (EBL) and less operative time than the SMP group ($P<0.0001$). While the time for starting weight bearing was considerably earlier in the SMPs group ($P<0.005$).

Conclusion Both FNs and SMPs can be used for fixation diaphyseal femoral shaft fractures; FNs offer shorter operating times and lower EBL, whereas SMPs require less time for weight bearing and union.

Keywords: Flexible intramedullary nail, Submuscular plate, Unstable diaphyseal femoral fracture.

INTRODUCTION

Femoral shaft fractures are among the most frequent fractures that necessitate hospitalization [(1)]. The treatment of juvenile femoral shaft fractures remains controversial, particularly when they are unstable (long oblique, spiral, or comminuted fractures) [(2)]. There are several alternatives for therapy, including various conservative and surgical approaches. Options for operational therapy include: Flexible intra-medullary nails (FNs), plate fixation, submuscular bridge plating, external fixation, and antegrade lateral trochanteric entrance nails. Operative treatment provides for firmer fixation, resulting in faster mobility and shorter hospital stays[(3)].Many factors influence the proper treatment strategy, including patient age, weight, fracture pattern, related injuries, surgeon, family preferences, and socioeconomic status[(3,4)]. FNs play an important role in treating this fracture type because they are a simple, load-sharing internal splint that permits movement and preservation of alignment and extremity length until a bridging callus forms with few complications[(5)]. Recently, The American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guidelines recommend submuscular plating (SMPs) for the treatment of diaphyseal femur fractures[(6)]. SMPs are advantageous because of their soft-tissue-preserving technique and relative stability, which allows for early range of motion (ROM) and quick healing [(4,7)].

The current study aimed to compare FNs and SMPs in the management of diaphyseal femoral fractures regarding clinical and radiological outcomes.

PATIENTS AND METHODS

This prospective randomized study was undertaken at the Orthopedic Department in Menoufia University Hospital and 6 October Health Insurance Hospital between Feb. 2021 and Feb. 2024.

This study was conducted on 30 children referred to the Orthopedic Department Emergency Room. Patients were randomly divided into two groups: **Group 1:** Patients treated by FNs (15 patients), **and Group 2:** Patients treated by SMPS (15 patients).

Inclusion criteria: Age between 5 and 12 years, closed unstable femoral shaft fracture, and intact neuro-vascular state.

Exclusion criteria: Open fractures, pathological fractures, NV. Injury and immuno-compromised patients. The patient's data were recorded: personal history, mechanism of injury, local, general, and clinical examination. Preoperative preparation includes splinting the affected limb, proper analgesia, and preoperative standard laboratory investigations.

Surgical technique: General anesthesia was used for all the children in this study. In the first group, preoperative planning for using titanium elastic nails pre-bent to achieve the goal of three-point fixation. The narrowest portion of the medulla was measured to determine the appropriate FNs thickness before surgery. Since two FNs were used, the nail thickness would be 40% of that diameter, resulting in an overall occupied medullary space of 80%, sufficient to provide good stability at the fracture site. The nail was selected as large, 3.5 mm and 4 mm in diameter. An opposing medial and lateral skin incision were made at the entry site 2 cm above the distal epiphyseal plate. Opening the medullary canal using an AWL angled obliquely within the medullary canal about 45°. The nails were introduced into the medullary canal till reaching the fracture site. Fracture reduction was done using manual traction under fluoroscopy. The nail was advanced to its final position (Fig. 1).

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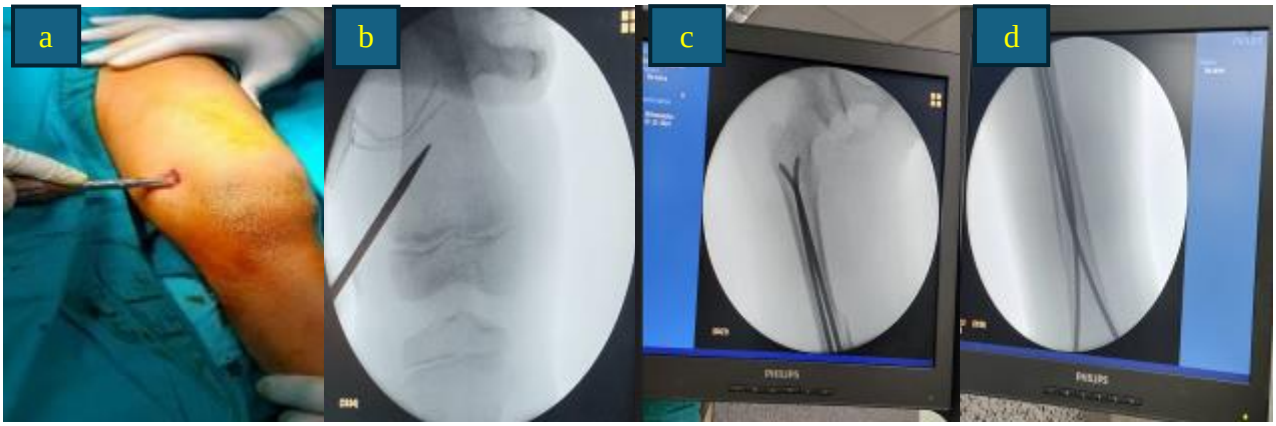

Figure (1): Steps of FN. a) Shows introducing the awl from skin incision. b) The direction of the awl into the medulla. c and d) The final position of the nail in the medulla.

The second group was fixed by submuscular plate. A 4.5 mm narrow or broad dynamic compression plate was used. The proximal and distal halves of the plate were curved using a plate bender to accommodate the proximal and distal femoral metaphyseal flares. The length of the plate was selected using fluoroscopy. Through a 3-cm proximal lateral skin incision, the plate was introduced sub-muscularly and epi-periosteally under direct visualization from proximal to distal. Fluoroscopy was used to establish the location of the plate's distal end, and a further incision was created at that level across from the plate's three distal holes. Reduction of the fracture was obtained by manual traction with readjustment the alignment and rotation under image guidance then the plate was fixed to the bone with three screws at each side of the fracture site (Fig. 2).

Figure (2): Steps of SMPs. a) Measuring the plate size and contour from outside on skin.
b) The proximal skin incision. c and d) The final position of the plate.

Postoperative protocol:

All patients were moved to the ward, where they were treated according to the following protocol, checking the neurovascular state of the limb operated, postoperative X-ray, analgesics and IV antibiotics were given for 2 doses in 24-hour hospital stay. At the 1st week: continuation of medication at home in the form of oral antibiotics, analgesic and anti-edematous. After 2 weeks, follow up the wound and removal of the sutures and X-ray follow up. Four weeks later follow up X-ray and starting regular exercises non weight bearing by performing static muscle exercises while in bed. After 2 months, X-ray follow up and starting weight-bearing according to apparent radiological union. After 6 months X-ray follow up. Final evaluation: the functional results were recorded according to Modified Flynn's criteria.

Ethical approval:

Menoufia Faculty of Medicine's Ethics Committee accepted this work. After receiving all of the information, all the caregivers of the participants signed their permission. The Helsinki Declaration was followed throughout the course of the investigation.

Statistical analysis

The statistical analysis was conducted using SPSS version 27.0. Data were represented as mean ± standard deviation (SD) and range. The Kolmogorov-Smirnov test was used to determine if the data were normal. Numbers and percentages were used to describe the qualitative data. The X^2-test was used to examine any relationships between categorical variables. When the anticipated cell count was fewer than five, the Fisher exact test was employed. Parametric data were compared between the 2 groups using independent t-test, while non-parametric data were compared using Mann-Whitney test. A p-value of less than 0.05 was regarded as significant. A p-value of less than 0.001 was regarded as highly significant.

RESULTS

The patients' history details and demographic data are presented in table 1. There was no statistically significant difference between the two groups regarding demographic data; age, gender, affected side, and fracture mechanisms.

Table (1): Demographic data of the studied groups.

	FNs group	**SMPs group**		
Gender			**Fisher Exact Test**	
Male	14 (93.3%)	12 (80%)	**χ^2 value**	**P value**
Female	1(6.7%)	3 (20%)	**1.154**	**0.598**
Age (years)			**Mann-Whitney Test**	
Mean ± SD	7.67 ± 2.16	8.87 ± 2	**MW-U= 69.0**	
Range	(5 - 12)	(5 - 12)	**P-value = 0.067**	
Side			**P-value = 1**	
RT	8 (53.33 %)	8 (53.33 %)		
LT	7 (46.67 %)	7 (46.67 %)		
MOT			**χ^2 value 0.958 Fisher exact test P value 0.949**	
RTA	5 (33.33 %)	6 (40 %)		
Twisting injury	4 (26.67 %)	2 (13.33 %)		
Direct trauma by a heavy object	2 (13.33 %)	2 (13.33 %)		
Fall on stairs	2 (13.33 %)	2 (13.33 %)		
FFH	2 (13.33 %)	3 (20 %)		

Regarding the mean C-Arm shots, there was no statistically significant difference between the two groups. In the FNs there were 10 patients (66.7%) with no LLD, 2 patients (13.3%) with LLD 1 cm and 3 patients (20%) with LLD 1.5 cm, while in SMPs there were 11 patients (73.3%) with no LLD, 3 patients (20%) with LLD 1 cm and 1 patient (6.7%) with LLD 1.5 cm. There was no statistically significant difference between both groups.

In the FNs group there were 4 patients (26.7%) developed angular deformity, while in SMPs, 2 patients (13.3%) developed angular deformity. There was no statistically significant difference between the two groups. There was also no statistically significant difference between the two groups regarding the time for union. The distribution of the Flynn score for the FNs and SMPs groups was identical. In both groups, 11 patients (73.3%) had an "excellent" score, while 4 patients (26.7%) had an "acceptable" score. This indicates that the results were similar in both groups, with no statistically significant difference in the Flynn score outcomes (Table 2).

Table (2): Parameters with no significant difference between both groups.

C-Arm shots				Independent t-test	
Mean ± SD		29.07 ± 11.44	37.27 ± 10.59	t-value	P-value
Range		(13 - 50)	(19 - 55)	2.038	0.0511
Time for union				Mann-Whitney Test	
Mean ± SD		7.07 ± 1.94	5.87 ± 1.77	MW-U= 73.5	0.106
Range		(4 - 10)	(4 - 8)		
Deformity	**No**	11 (73.3 %)	13 (86.7 %)	χ^2 value 3.14	Fisher exact test P-value 0.397
	3º varus	1 (6.7 %)	0 (0.0%)		
	5º varus	2 (13.3 %)	0 (0.0%)		
	5º valgus	1 (6.7 %	2 (13.3 %)		
LLD	**0 cm**	10 (66.7%)	11 (73.3%	Chi-square Fisher Exact Test	
	1 cm	2 (13.3%)	3 (20%)	χ^2 value 1.248	P-value 0.727
	1.5 cm	3 (20%)	1 (6.7%)		
Flynn's score	**Excellent**	11 (73.3 %	11 (73.3 %)	χ^2 value= 0 P-value= 1	
	Satisfactory	4 (26.7 %)	4 (26.7 %)		
	Poor	0 (0 %)	0 (0 %)		

The mean intraoperative blood loss and the operative time in the FNs group were statistically significantly less than in the SMPs group. While, the weight-bearing time in the FNs group was statistically significantly longer than in the SMPs group, showing the superiority of SMPs regarding the time for weight bearing.

Table (3): Parameters with statistically significant difference between both groups.

	FNs group	SMPs group	Mann-Whitney Test
Blood loss (ml)			
Mean ± SD	51.67 ± 9.57	173.33 ± 39.94	MW-U= 0.00
Range	(40 - 70)	(120 - 250)	<0.0001
Operative time (min)			
Mean ± SD	32.33 ± 6.51	67.33 ± 11.47	MW-U= 0.00
Range	(25 - 45)	(50 - 90)	<0.0001
Time for weight bearing (weeks)			Mann-Whitney Test
Mean ± SD	9.07 ± 1.94	6.73 ± 1.83	MW-U= 46.0
Range	(6 - 12)	(5 - 9)	0.005

CASE PRESENTATION

Case 1: Male 10 years old fall from height. P. X-Ray AP/L views showed closed spiral fracture shaft left femur, intact NV bundle. Free medical and surgical history. The patient was treated with SMPs. Patient was followed up at the outpatient clinic. A series of follow-up visits were conducted to assess functional and radiological outcome. Radiological callus and fracture union were complete after 6 weeks. Partial weight bearing started after 6 weeks. Full weight bearing started after 8 weeks. Flyn's score was excellent.

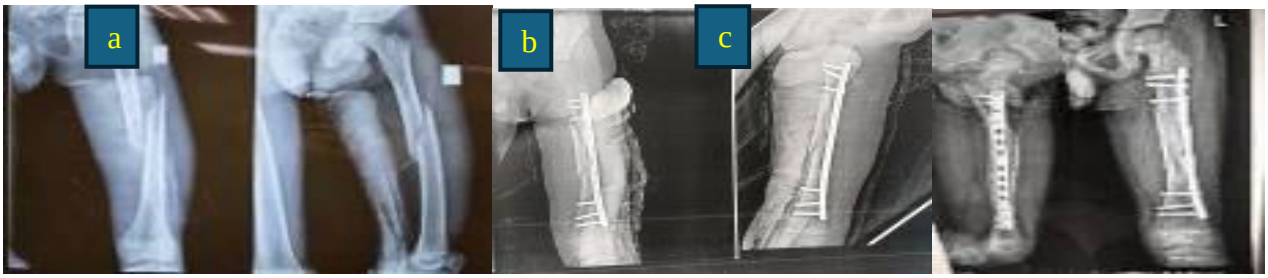

Figure (3): P. X-rays showing (a) pre op., (b) post op. and (c) after 5 months.

Case 2: Female 7 years old presented with comminuted fracture shaft right femur after RTA. As shown in X-ray AP/L views. The fracture was closed with an intact NV bundle. Medical and surgical history was free. The patient was treated with flexible nail. Patient was followed up at the outpatient clinic. A series of follow-up visits were conducted to assess functional and radiological outcome. Radiological callus and fracture union were complete after 8 weeks. Partial weight bearing started after 8 weeks. Full weight bearing started after 10 weeks. Flyn's score was excellent.

Figure (4): Series of X-rays showing (a) pre op., (b) post op., (c) after 2 months and (d) post removal.

DISCUSSION

In the past few decades, the treatment of pediatric femur fractures, particularly in children older than five, has tended to involve surgery, as opposed to conservative care, which aimed to promote quicker recovery and shorter immobilization. Operative treatments are also appropriate to prevent complications that could be physical, social, or psychological. There is a great deal of debate regarding the best course of treatment between the various available fixation techniques [8].

Many surgeons are encouraging intramedullary fixation, which has grown in popularity. This allows for functional reduction and stable three-point fixation that permits relative stability with micro-motion. Applying elastic, stable IM (FNs) promotes healing and union [8].

Submuscular bridge plating also provides acceptable fracture reduction and relatively stable fixation, with a minimally invasive soft tissue preserving technique, allowing early mobilization and ROM [9].

This study compared the functional and radiological outcomes of using FNs and minimally invasive SMPs to fix femur fractures in 30 children aged five to twelve. The study patients were sub-grouped; in group 1 (FNs), there were 14 males and one female, ranging from five to twelve years old. In group B (SMPs), there were 12 males and three females, ranging from five to twelve years old. The male-to-female total ratio in the current study is 6:1, like that of **Chen *et al.*** [9]. This gender gap may be explained by the fact that boys participate in sports and outdoor activities more frequently than girls.

In the current study**,** the mean operative time in the FNs group was 32.33 ± 6.51 minutes, while in the SMPs group, it was 67.33 ± 11.47 minutes. There was a statistically significant difference between the two groups ($P < 0.0001$). This was comparable to **El-Adly *et al.*** [7] who showed that FNs op. time is about 45.4±10.5 min and SMP about 60±11.5 min. Also, the mean op. time in **Chen *et al.*** [9] was about 52 ± 22 min. in FNs and 94 ± 34 min. in SMP.

In the current study**,** the mean intraoperative blood loss in the FNs group was 51.67 ± 9.57 ml, while in the SMPs group it was 173.33 ± 39.94 ml, with a statistically significant difference between both groups ($P < 0.001$) showing the little amount of blood loss in FNs group. This is like **El-Adly *et al.*** [7] as they reported that mean intraoperative blood loss was 12.44 ± 4.7 ml in FNs, while 67.56 ± 16.7 ml in SMPs. **Sultan *et al.*** [10] also reported similar results, with 92 ml intra-operative blood loss in FNs and 187 ml in SMPs. Similarly, **Li *et al.*** [11] reported extensive blood loss in SMPs (106.4±26.6) than FNs (51.7±18.9). All studies stated that SMPs are more associated with extensive blood loss than FNs.

Regarding the mean intraoperative C-Arm shots, in the current study, there were 29.07 ± 11.44 shots in the FNs group. In the SMPs group, the mean C-Arm shots were 37.27 ± 10.59. There was no statistically significant difference between the two groups ($P=0.051$). **Li *et al.*** [11] reported that there was no significant difference between ESIN (20.9±5.0) and SMP (21.7±5.0) for the primary surgery ($P=0.42$). **El-Adly *et al.*** [7] reported little difference between the results of the two groups; ESIN (45±7.4) shots and SMP (50±10.6) shots.

Regarding Flynn's Score, our study recorded that: 11 patients (73.3%) got an excellent score in both groups, and four patients (26.7%) got an acceptable score. There were no patients in both groups who had poor results.

El-Adly *et al.* [7] reported that the functional outcomes according to the Flynn score of two groups (50 patients, 25 in each group) were as follows: FNs: Excellent, 19 patients (76%), Satisfactory, 6 patients (24%), Poor, 0 patients (0%). **SMPs**: Excellent 23 patients (92%), Satisfactory 2 patients (8%), Poor 0 patients (0%).

Hayat *et al.* [12] reported that the functional outcomes according to the Flynn score of two groups (102 patients, 51 in each group) were as follows: FNs: Excellent, 37 patients (72.5%), Good, 13 patients (25.5%), Fair, 1 patient (2%). **SMPs**: Excellent 47 patients (92.2%), Good 4 patients (7.8%).

Li *et al.* [11] in their study found a difference in the number between the 2 groups. FNs: All were 77 patients; the excellent rate was (42/77, 54.5%), and the excellent + satisfactory rate was (76/77, 98.7%). SMPs: All were 45 patients; the excellent rate was (40/45, 88%), and the excellent + satisfactory rate was (44/45, 97.8%).

As regards angular deformity in our study, four patients (26.7%) developed angular deformity in the FNs group: 1 (6.7 %) with 3^0 varus, 2 (13.3 %) with 5^o varus, and 1 (6.7 %) with 5^o valgus, while in SMPs, 2 (13.3%) patients developed angular deformity (5^o valgus). The two groups had no statistically significant difference (P value = 0.493). All patients with deformity had the same history of relative encouragement to bear weight early.

Li *et al.* [11] reported no degree of angulation among the plate group, and 4 patients (5.2%) developed mild angulation degrees.

El-Adly *et al.* [7] reported that, after six months of patient follow-up, there were four cases of malalignment (16%) in the FNs group and eight in the SMPs group; the malalignments were less than 10 degrees varus angulation.

In our study, 5 patients (33.35%) had LLD in the FNs group, 2 patients (13.3%) had 1 cm LLD, and 3 patients (20%) had 1.5 cm LLD. In the SMP group, there were 4 patients with LLD, 3 patients (20%) with 1 cm LLD, and 1 patient (6.7%) with 1.5 cm LLD. In the literature, **Sultan *et al.*** [10] reported roughly that there is no evidence of leg-length discrepancy > 2 cm, and **El-Adly *et al.*** [7] reported that the length

discrepancy in the FNs group was about (1.25±0.4) cm, in the SMPs group was about (0.75±0.1) cm, with a P value of 0.12.

Li *et al.* [11] reported that roughly 4 patients in the FNs group developed mild angulation and 0 patients in the SMPs group.

LIMITATIONS

This study had some limitations, such as the small sample size, short follow-up time, and the fact that it was conducted at only two centers. The removal of the implant and its complications were not recorded, and there was no follow-up after removal.

CONCLUSION

Both FNs and SMPs are reliable methods for fixing diaphyseal femoral shaft fractures; FNs offer shorter operating times, and lower EBL, whereas SMPs require less time for weight bearing and union.

RECOMMENDATION

There were some recommendations after this study to increase the number of cases, take longer time for follow-up, perform the study at multi center, recording the removal and its complication and record the follow up after removal.

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No conflict of interest.

REFERENCES

1. **Galano G, Vitale M, Kessler M *et al.* (2005):** The most frequent traumatic orthopedic injuries from a national pediatric inpatient population, Journal of Pediatric Orthopedics, 25: 39–44.
2. **Loder R, O'Donnell P, Feinberg J (2006):** Epidemiology and mechanisms of femur fractures in children. Journal of Pediatric Orthopedics, 26(5):561–66.
3. **John M. Flynn and David L (2015):** Skaggs. In: Peter M. Waters MJMF and DLS, editor. 8th ed., Philadelphia: Rockwood and Wilkins Fractures in Children, pp. 990–1013. DOI:10.1007/s00590-015-1690-6
4. **Chen L, Sullivan B, Sponseller P (2018):** Submuscular plates versus flexible nails in preadolescent diaphyseal femur fractures. J Child Orthop., 12(5):488–92.
5. **Curran P, Albright P, Ibrahim J *et al.* (2020):** Practice patterns for management of pediatric femur fractures in low- and middle-income Countries. Journal of Pediatric Orthopaedics, 40(5): 251–258.
6. **Flynn J, Hresko T, Reynolds R *et al.* (2001):** Titanium elastic nails for pediatric femur fractures: a multicenter study of early results with analysis of complications. Journal of Bone & Joint Surgery, 21(1):4–8.
7. **Oetgen M, Blatz A, Matthews A (2015):** Impact of clinical practice guideline on the treatment of pediatric femoral fractures in a pediatric hospital. Journal of Bone and Joint Surgery, 97(20):1641–46.
8. **El-Adly W, El-Gafary K, Khashaba M *et al.* (2022):** Flexible intramedullary nail versus submuscular locked plate with the cluster technique in pediatric femoral shaft fractures fixation. Indian J Orthop., 56(4):580–86.
9. **Carey T, Galpin R (1996):** Flexible intramedullary nail fixation of pediatric femoral fractures. Clinical Orthopaedics and Related Research, 332: 110–18.
10. **Chen L, Sullivan B, Sponseller P (2018):** Submuscular plates versus flexible nails in preadolescent diaphyseal femur fractures. J Child Orthop., 12(5):488-92.
11. **Sultan A, Haq I, Rashid S *et al.* (2023):** Complications of plate fixation of femoral shaft fractures in children and adolescents. International Journal of Orthopedics, 6(1): 771-79.
12. **Li J, Rai S, Ze R *et al.* (2020):** The optimal choice for length unstable femoral shaft fracture in school-aged children: A comparative study of elastic stable intramedullary nail and submuscular plate. Medicine (Baltimore), 99(25): e20796. https://doi.org/10.1097/MD.0000000000020796
13. **Hayat U, Gillani S, Masood F *et al.* (2021):** Comparison of submuscular locking plate and titanium elastic nail in children with fracture midshaft of the femur. Pakistan J Med Health Sci., 15: 209-12.