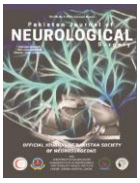

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Original Article

Comparison of Surgical Versus Conservative Management of Borderline Traumatic Extradural Hematomas without Neurological Deficit

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ABSTRACT

Objective: To compare the outcome of surgical versus conservative treatment of traumatic extradural hematoma in the supratentorial regin.

Material and Methods: It was a prospective randomized controlled trial conducted in Departments of Neurosurgery, Allied Hospitals, Faisalabad between December 2019 to November, 2020. A total of 100 patients Supratentorial EDH; fulfilling the selection criteria were enrolled. All patients underwent clinical and radiological assessment of EDH volume by the same neurosurgical team. The patients were then divided randomly into two groups by using the lottery methods. Group A patients were conservatively managed. Group B underwent surgery. All surgeries were done by the same surgical team. Glasgow outcome scale was noted in 5 days after admission or surgery in both groups.

Results: The patients average age was 29.96 years, male to female ratio was 1.7:1. The mean volume of hematoma was 24.68 and 27.56 in group A (conservative group) and Group B (operated group) respectively. The favorable outcome was noted in all the patients and no mortality occurred in any patients.

Conclusion: Both surgical and conservative treatments are equally effective in terms of a favorable outcome and mortality occurrence in management of traumatic EDH <30ml without neurological deficit. The conservative treatment is safe and cost-effective in borderline patients.

Keywords: Mortality, Conservative, Surgery, Traumatic Extradural Hematoma.

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INTRODUCTION

This study was conducted to compare the outcomes of surgical versus conservative treatment of traumatic extradural hematoma without neurological deficit. Treatment for post-

traumatic patients with large extradural hematomas with the progressive neurological deficit is a surgical intervention for an excellent prognosis. Small hematomas without neurological deficits also give no difficulty in the decision of conservative management. In patients with the borderline volume of extradural hematomas without any progressive neurological deficit or life-threatening condition decision of surgery is difficult.

In adults less than 45 years of age, trauma is considered to be one of the main causes of death. Specifically, head injury is the leading cause of trauma-mediated mortalities. Extradural hematomas are important in the prognosis of serious head injuries, despite the fact that these hematomas are rare in patients with head injuries (1%) and in patients who are in comatose (10%).[1]

After injury to the head, a layer of blood accumulates between the rigid skull and the outer endosteal layer of the dura mater. The sudden blow to the head shakes the brain and commonly renders unconsciousness in many patients of EDH. It is followed by a brief recovery of consciousness (the lucid interval), and another episode of loss of consciousness. This second episode of loss of consciousness is due to the continuous expansion of hematoma which compromises the abilities of intracranial structures to compensate for the rise in intracranial pressure. If this process goes on it will lead to a decompensated rise in ICP and complicate in to hypoxic seizures, hemiparesis and herniation, and death. In cases when EDH is stable, and it attains a maximum size within a few minutes of injury patient may not have a secondary expansion of hematoma, and the above-mentioned complications. In such cases, clear-cut guidelines are lacking and it is the surgeon's choice whether to operate or manage conservatively.

Extradural collections of 10 – 15 ml usually do not render any clinical deficits or loss of consciousness, and patients have a good outcome. A small EDH of 10 – 15 ml usually does not cause any neurological problems, and it has a good prognosis. However, the sudden expansion of an EDH could worsen the patient's condition rapidly.[2] This may lead to death or a serious neurological disorder, due to this reason attention and quick intervention are keys in the prevention of such unwanted circumstances.[3]

Very few studies have been conducted on the management of EDH locally. Khan et al[4] mentioned in their study that epidural hematoma less than 30 ml volume may not need surgery. He also concluded that in EDH of a non-dangerous area in a patient with a good general condition may be managed conservatively. The threshold of conversion to surgery decreases in the volume of even 10 ml if GCS is low and hematoma is in the temporal region.[5]

Bhau et al[6] in their study discussed the cause of conversion from conservative to surgical management. They emphasized the role of both clinical indicators like Cushing's triad and radiological parameters like the expansion of EDH on CT scan in a change of management at any time.

The use of computed tomography leads to accurate and prompt EDH diagnosis. However, there are mixed views about the role of surgical treatment for EDH, whether it leads to a quick and complete recovery. Also, there are mixed data about the potential of non-operative management.[7]

In some circumstances, EDH may run a chronic course and is detectable after a few days of injury. A patient diagnosed with small EDH may be subjected to conservative treatment as indicated by the neurological observation.[8]

The objective of this 'study was to compare the outcomes of surgical versus conservative treatments of traumatic EDH. In the literature, it is reported that patients presenting with head injuries, surgical management of EDH can be prevented depending on the volume of hematoma < 30 ml. But there is no local data

available regarding the extent of the problem in the local population. If conservative management has a better outcome or at least equal to surgical outcome in patients with hematoma volume ≤ 30 ml, then in the future such cases will be managed conservatively and unnecessary surgeries can be prevented. This will help to reduce the burden of hospitals and surgeons by reducing unnecessary surgeries for traumatic EDH ≤ 30 ml volume.

MATERIAL & METHODS

Study Design & Setting

It was a randomized controlled trial conducted at Department of Neurosurgery, Faisalabad Medical University, Allied Hospital, Faisalabad from December 2019 to November 2020. After approval from ethical committee, a total of 100 patients meeting the inclusion criteria were enrolled from Emergency Department the hospital.

Patients' Groups

The patients were divided in Group-A and included 50 cases which were conservatively managed and Group-B included 50 cases which were surgically managed. The 50 cases in each group were calculated with 180% powers of study, 5% level of significances & takings expected % of mortality (14.7%) 'with surgical treatment & 0% with conservative management by using following formula:

$$n = \frac{\left\{ z_{1-\alpha}\sqrt{2\bar{P}(1-\bar{P})} + z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)} \right\}^2}{\left(P_1 - P_2\right)^2}$$

Where, P12 = proportions of sample 12 = 10.147, P22 = proportions of sample 22 = 10.0, $Z_{1-\alpha 2}$ = Level of significance = 295% =21.96 $Z_{1-\beta 2}$ = powers of study = 80% = 1.282. The sampling technique used was non-probability, consecutives samplings

Inclusion Criteria

Patients included with ages between 16-60 years of either gender presenting 'with' supratentorial EDH with hematoma volume, ≤ 30 ml, and GCS 13/15.

Exclusion Criteria

Patients with GCS < 10 on presentation with midline shift equal or more than 5 mm, volume more than 30 ml, patients with additional intracranial injuries like a contusion, intracerebral hematoma, post craniotomy hematoma (medical record), and patients with bleeding or diathesis were excluded. Posterior fossa EDH were also excluded.

Data Collection

100 patients fulfilling the selection criteria were enrolled in the study from the Emergency Department of Allied Hospital, Faisalabad. After informed consent demographic information (name, age, gender, cause of injury including road traffic accident, fall from height, fight, and duration of injury) was obtained. All information was noted on pre-designed proforma.

Surgical Management & Follow-up

All patients underwent an assessment on CT scan to measure the EDH volume and volume was noted. Afterward, the patients were 'randomly divided in two groups by 'using 'the lottery method.' In group A, the patients underwent conservative management. In group B, patients undergo surgery. Surgeries were done by the same neurosurgeon. After the procedure, patients were moved to the postsurgical ward & were followed-ups for 5 days. During 5 days, the Glasgow outcome scale was noted. In case of death, recorded as mortality. Data 'was analyzed by SPSS V 25. Means and SD was 'calculated for quantitative variables like age (16 – 60 Year),

duration of injury and GCS (12/15) score and size of hematoma ≤30ml at baseline.

Data Analysis

Frequency and percentages were calculated for a qualitative variable like gender, cause of head injury, and outcome (favorable outcome and mortality). Both groups were compared for outcome by using the chi-square test. P-value ≤ 0.05 was considered significant. Data was stratified for age, gender, duration of injury, cause of injury, and baseline GCS score. Post-stratifications, chi-square, and t-test were applied to compare outcomes on both groups for each stratification. P-value less than 10.05, was considered as 'significant.

RESULTS

Age Distribution

The patients' age was ranged between 16 to 60 years with mean age of 29.96 ± 10.88 years. Among conservative management group A, the average age of the patients was 28.80 ± 10.72 years, which was not far different from surgically managed group B i.e., 31.12 ± 11.03 years **(Table 1).**

Table 1: Age distribution.

Age – Years (N)	100	Group A n=50	Group B n=50
Mean	29.96	28.80	31.12
SD	10.88	10.72	11.03
Minimum	16.00		
Maximum	60.00		

Gender Distribution

64% were male and 36% were female patients. The male-to-female ratio was 1.7:1. In group A, 36 (72%) patients were males & 28 (56%) patients 'were females in contrast to the B group, where 14 (82%) patients were male and 22 (44%) patients were females **(Table 2)**.

Table 2: Frequency distributions of gender between study groups.

		Study Groups		Total
		Conservative	Surgical	
Genders	Males	136	28	64
		172.0%	56%	64%
	Females	114	22	36
		128.0%	44.0%	36%
Total		50	50	100
		100.0%	100.0%	100.0%

Duration of Injury

On average, the 'patients were able to reach within 5.09 ± 3.31 hours of injury with minimum & maximums durations of injury of 1 & 11 hours respectively. In group A, the average duration of injury was 4.32 ± 2.77 hours, whereas in the B group the average duration of injury was 5.86 ± 3.63 hours. This difference was statistically significant. i.e. p-value = 0.019 **(Table 3)**.

Cause of Injuries and Treatments

The road traffic accidents were found in 34 (34%), history of fall was found 40 (40%), and the injury due to fight was observed in 26 (26%) patients. Among road traffic accident patients, 17 (34%) patients were treated conservatively and 17 (34%) patients received surgical intervention. Among patients who had an injury due to fall, 24 (48%) patients fell in group A and 16 (32%) patients were treated with surgical methods. Similarly, among patients having injury due to fight, 9 (18%) patients were treated conservatively and 17 (34%) patients were treated with surgical method. This comparison showed the statistically insignificant result, i.e., p-value =20.131 **(Table 4)**.

Baseline GCS Scores

The results of our study showed that the average baseline GCS score of the patients was 13.59 ±

0.59 with minimums & maximums GCS scores of 13 & 15. In group A, the mean baseline GCS score of the patients was 13.44 ± 0.61, while in the B group the mean baseline GCS score of the patients was 13.28 ± 0.57. This comparison showed the statistically insignificant result, i.e., p value = 20.4996 **(Table 5)**.

Mean Volume of Hematoma

According to this study, the mean volume of hematoma of the patients was 26.12 ± 2.99 ml with a minimum and maximum volume of hematoma of 20 & 30 ml, respectively (**Table 6**). In our study, in the conservative management group, the means volume of hematoma 'was '24.68 ± 2.41 ml, while in the surgical management group, the means volumes of hematoma of then patients was 27.56 ± 2.84 ml. This comparison showed a statistically significant difference. i.e. p-value < 20.001 **(Table 6)**. A favorable outcome was noted in all the patients and no mortality occurred in any of the patients **(Table 7)**.

Table 3: Summary statistics of duration of injury (hours).

	N	100	Group A n=50	Group B n=50	p-value	t-test/df
Duration of Injury (Hours)	Mean	5.09	4.32	5.86	0.019	2.38;98 CI: -2.82 to -0.25
	SD	3.31	2.77	3.63		
	Minimum	1.00				
	Maximum	11.00				

Table 4: Comparisons of Causes of Head Injury Between the Groups.

		'Study' Groups Conservative	Surgical	Total	p-value	χ^2
Causes of Head Injury	RTA	17	17	34	0.131	4.0615
		34.0%	34.0%	34.0%		
	Fall	24	16	40		
		48.0%	32.0%	40.0%		
	Fight	9	17	26		
		18.0%	34.0%	26.0%		
Total		50	50	100		
		100.0%	100.0%	100.0%		

Table 5: Summary- Statistics of Baseline GCS.

	N	100	Group A n =50	Group B n =50	p-value	t-test/df
Baseline GCS	Mean	13.36	13.44	13.28	0.4996	0.677;98 CI:-0.15 to 0.313
	SD	0.59	0.61	0.57		
	Minimum	13.00				
	Maximum	15.00				

Table 6: Summary – Statistics of Volume of Hematoma (ml).

	N	100	Group A n =50	Group B n=50	p-value	t-test/df
Volume of Hematoma (ml)	Mean	26.12	24.68	27.56	<0.001	5.46;98 CI: -3.92 to -1.83
	SD	2.99	2.41	2.84		
	Minimum	20.00				
	Maximum	30.00				

Table 7: Frequency Distribution of Favorable Outcome & Mortality.

		Frequency	Percentage
Favorable Outcome	Yes	100	100%
Mortality	No	100	100%

DISCUSSION

In young adults or children, head injury is the most significant reason for poor outcomes or death. EDH following head trauma is common and if treated promptly, can have a good prognosis.[9-11] In this study, the patients appearing with road traffic accident were 34 (34%), the patients had an injury because of fall were 40 (40%) and the injury due to fight was observed in 26 (26%) patients. The average baseline GCS was 13.59 ± 0.59. In the conservative management group, the mean baseline GCS score of the patients was 13.61 while in the surgical management group the mean baseline GCS score of the patients was 13.28 ± 0.57 (p-value = 0.180). In the conservative management group, the mean volume of hematoma was 24.68 ± 2.41. It was 27.562.84 ml (p-value = < 0.001) in the surgical group. However, both groups are statistically equally effective in terms of favorable outcomes and mortality of the patients.

Bullock et al[12] studied extradural hematoma in 22 patients (12 to 38 ml in volume), all were managed conservatively. The hematoma resolved on its own, as observed on CT scans, resulting in good neurological recovery over a period of 3 – 15 weeks.

One study showed that a favorable outcome was achieved in 75.6% of patients, underwent surgical management while 93.6% of patients underwent conservative management (p = 0.007). The rate of mortality was also significantly high with surgical management (14.7%) while nil (0%) with conservative management (p = 0.005).[13]

Pozzati et al[14] published their study on 22 patients with EDH who were also managed conservatively. All these were either asymptomatic or had minor neurological findings at the time of admission.

2 cases were reported by Weaver et al.[15] 1 patient had a temporal EDH who was CT scanned 16 hours after injury, & the others remained undiagnosed for 3 days. Later his CT scan showed a temporal-parietal EDH. Both were conservatively treated & the hematomas 'resolved 'spontaneously by 30 & 49 days, respectively.

Zakaria et al[16] in 12013 studied three patients with EDH and their treatment strategies, with a special emphasis on surgical and conservative treatment. They stated that the management of EDH could be done in a conservative manner, provided that the Glasgow Coma Scale does not change with the symptomatic improvement of the patients.

Chen Tzu-Yung et al[17] studied 74 patients with EDH following trauma, having GCS > 12 and were conservatively managed; 14 subsequently underwent surgical evacuation. Those that required surgery had a significant supratentorial hematoma (volume greater than 30ml) causing more than 5 mm midline shift and the hematoma was thicker than 15mm.

CONCLUSION

We concluded that:

1. This study showed that in selected patients both surgical and conservative treatments are equally effective in terms of a favorable outcome and mortality occurrence in management of traumatic EDH < 30 ml. The conservative treatment is safe and cost-effective so it is suggested that the patients should be treated with the conservative method.
2. The role of surgical intervention in management cannot be denied in the treatment of EDH, especially in patients with progressive neurological deficits and in those patients where blood collection is in dangerous areas like the temporal and posterior fossa.

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Additional Information

Disclosures: Authors report no conflict of interest.
Ethical Review Board Approval: The study was conformed to the ethical review board requirements.
Human Subjects: Consent was obtained by all patients/participants in this study.
Conflicts of Interest:
In compliance with the ICMJE uniform disclosure form, all authors declare the following:
Financial Relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work.
Other Relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

AUTHORS CONTRIBUTIONS

Sr.#	Author's Full Name	Intellectual Contribution to Paper in Terms of:
1.	Muhammad Abd-ur-Rehman	Study design and methodology.
2.	Nasir Mahmood Ali	Paper writing, referencing, and data calculations.
3.	Talha Abbas	Data collection and calculations.
4.	Khurram Zafar	Analysis of data and interpretation of results etc.
5.	Haseeb Ahmad	Literature review and manuscript writing.
6.	Qura Tul Ain Tariq	Analysis of data and quality insurer.
7.	Zain Ali	Data Collection and analysis.
8.	Muhammad Qasim	Data Collection and analysis.