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ORIGINAL ARTICLE

A Prospective Study Comparing Subperiosteal Versus Subdural Drain After Burr-hole Drainage of Chronic Subdural Hematoma

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Abstract

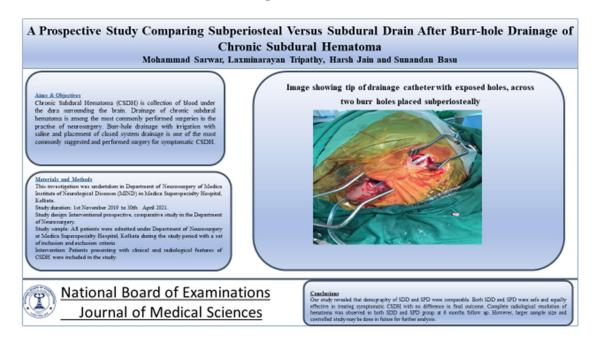
Aims: The aim of our study was to perform a comparison between the efficacy of subperiosteal drain and subdural drain, and to evaluate any differences in terms of functional outcome in the treatment of symptomatic CSDH. Materials and Methods: The interventional, prospective, comparative study was undertaken in Department of Neurosurgery of Medica Institute of Neurological Diseases (MIND) in Medica Superspecialty Hospital, Kolkata, between 1st November 2019 to 30th April 2021, with set inclusion and exclusion criteria. Primary outcome was based on recurrence with 6 months. Secondary outcomes were incidence of re-operation and complications. 44 cases were distributed according to computer generated random numbers for the insertion of either drain following evacuation of CSDH. The data were analysed with SPSS software for windows version 21.0. Results: Our study has shown good outcomes in both groups at 3 months and 6 months. P values of Glasgow outcome score at discharge, 1 month, 3 months, and 6 months were 0.064, 0.39, 0.54 and 0.31; none of them were statistically significant. Conclusion: Our study revealed that both SDD and SPD were safe and equally effective in treating symptomatic CSDH with no difference in final outcome. Complete radiological resolution of hematoma was observed in both SDD and SPD groups at 6 months follow up. However, large sample size and controlled study may be done in future for further analysis.

Keywords: chronic subdural hematoma, CSDH, subdural drain, subperiosteal drain

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Graphical Abstract



Chronic Subdural Hematoma (CSDH) is collection of blood under the dura surrounding the brain. Drainage of chronic subdural hematoma is among the most commonly performed surgeries in the practise of neurosurgery. Burr-hole drainage with irrigation with saline and placement of closed system drainage is one of the most commonly suggested and performed surgery for symptomatic CSDH.

CSDH is commonly a disease of the geriatric population which is linked to significant morbidity and death. The occurrence of CSDH is approximately 19 per 1,00,000 population in the age group of 65-74 years, increasing to 47-153 per 1,00,000 population in patients older than 75 years [1].

The pathophysiology of CSDH was primarily theorised by Virchow [2] in 1857, when he first used the phrase "pachymeningitis haemorrhagica interna" that determined that dural inflammation was present and haemorrhagic elements.

McKissock et. al. [3] clinically defined CSDH as hematoma presenting after 20 days following trauma, resulting in the observation of dark crimson liquid blood encircled by a thin capsular membrane after surgery. Previously SDH was classified according to the appearance of density on computed tomography (CT) scans as hyperdense in acute SDH, as isodense on CT in subacute and hypodense in case of CSDH.

There are There are several surgical techniques used to treat this problem, including craniotomy, burr-hole craniostomy, and twist drill craniostomy. The gold standard of treatment, however, remains Burr-hole craniostomy and the hematoma's drainage and the installation of a drain. Patients without any symptoms and no radiological signs of a mass effects are managed conservatively with repeated CT ongoing scans and follow-ups. Spontaneous resolution of CSDH has also been described. Recent treatment modality

of refractory or recurrent middle meningeal artery embolisation as a persistent subdural hematoma has gained momentum. Al-Mufti (2021) [4] has studied on safety and efficacy of diluted n-butyl cyanoacrylate (n-BCA) for middle meningeal artery embolization.

Due to longer life expectancies, particularly in developing nations, there has been a noticeable increase in the number of patients presenting with symptomatic CSDH in recent years. (Baechli et al. 2004 [1]). Additionally, it is primarily diagnosed in elderly people who have concomitant medical disorders that may have a simultaneous role in its development. There aren't much class II evidence publications on the management of CSDH in the literature as of now. According to general consensus, burr-hole craniostomy together with irrigation and the installation of a closed drainage system is the preferred surgical procedure for symptomatic CSDH. (Weigel et al. 2003 [5]). Santarius et al. (2009) [6] found that after burr-hole evacuation of CSDH, the installation of a subdural drain was linked to a lower risk of recurrence and death. This was based on a randomised controlled experiment.

A significantly less invasive technique has been documented in more recent research, which involves using a subperiosteal drain rather than a traditional subdural drain (Gazzer et al. 2007 [7], Zumofen et al. 2009 [8], Bellut et al. 2012 [9]). This is because of implantation in a subdural drain on the cortical brain surface may result in problems like haemorrhage, seizures, and infection at the surgical site (e.g., Empyema).

The placement using a subperiosteal drain is advised for individuals who have a known high risk of problems, particularly

those who are older than 80 (Bellut⁹ et.al 2012).

We planned to investigate a sample size of 44 patients (22 in each group) using a prospective study design in order to show the variation in overall results and the rate of hematoma recurrence.

Material and Methods

This investigation was undertaken in Department of Neurosurgery of Medica Institute of Neurological Diseases (MIND) in Medica Superspecialty Hospital, Kolkata.

Study duration: 1st November 2019 to 30th April 2021.

Study design: Interventional prospective, comparative study in the Department of Neurosurgery.

Study sample: All patients were admitted under Department of Neurosurgery at Medica Superspecialty Hospital, Kolkata during the study period with a set of inclusion and exclusion criteria

Intervention: Patients presenting with clinical and radiological features of CSDH were included in the study.

The collected demographic and clinical variables included age, sex, comorbidities like history of hypertension, diabetes mellitus, coagulopathy, hepatic, renal and cardiac diseases and medications (antihypertensive and antiplatelet or anticoagulant agents).

Blood pressure, pulse and respiration rate were recorded.

Glasgow Coma Score (GCS) was recorded.

Detailed history was obtained of any co-morbidities, history of trauma (exact date, significant or non-significant), previous brain surgeries.

Midline shift was noted on imaging.

Bilateral chronic subdural hematomas were considered as one case.

Routine investigation data such as haemoglobin, total leucocyte count, platelet count, PT, INR, blood sugar, serum urea, creatinine was collected.

Anaesthesia check-up was done in patients for surgery

Consent for surgery and anaesthesia was taken in each case.

Length of intensive care unit (ICU) stay and in the length of hospital stay was recorded.

Follow up period: The patient's clinical outcome was assessed by Glasgow Outcome Scale (GOS) on discharge, 1 month, 3 months, and 6 months follow up. Poor clinical outcome was defined as GOS <4. Mortality, morbidity and quality of life were recorded in follow-up clinic with a structured questionnaire.

Surgical Techniques

A proper informed permission form, outlining the indications and hazards of the research procedure, was obtained from the patient or their immediate family members or carers before to surgery. Anticoagulants anti-platelet drugs used and operatively were excluded ahead of surgery, and FFP and vitamin K injection IM administered to establish normal clotting parameters. AEDs was given to all patient who presented with seizures as well as prophylactically to rest of the patients. In that case, IV Levetiracetam loading dose maintenance dose given. preference of AED was Levetiracetam in all cases.

The following steps were taken during surgery:

The patient was given local anaesthesia (LA) / monitored anaesthesia care (MAC) during surgery.

With their head supported by a rubber horseshoe, the patient was put in a supine position headrest.

The area of incision was marked at level of maximum subdural collection at frontal and parietal region then covered with sterile surgical drapes after being cleansed with Povidone iodine.

single shot of antibiotic prophylaxis 1.5 g of IV Cefuroxime (Supacef, Glaxo SmithKline Pharmaceuticals Ltd) and Local Anaesthetic (Lignocaine + Adrenaline) was given to each patient prior to skin grafting and Cefuroxime continued for 48 hours afterward (till drain was removed, whichever was later).

Two burr-holes were created at the maximum thickness of the clot, using a burr-hole craniostomy size that (measures at least 10mm x 10mm in diameter) around 6-8 cm apart.

Coagulation caused the dura mater to expand up widely in cruciate fashion according to the burr-hole's size.

Body irrigation was used during intraoperative subdural irrigation temperature when the discharge was clean, use regular saline.

The closed-system drainage was installed either with subperiosteal drain or subdural drain selected according to sequence of computer-generated random numbers.

When the SPD system was installed, a Romovac catheter (14 F) was positioned across the burr-hole in the subgaleal plane. In case of placement of the SDD system, a Jackson-Pratt drain (flat) catheter was negotiated through the burrhole and gently placed in the subdural space.

Either drain was attached to a collecting tube after being drawn through a

tiny skin incision posterolateral to the burrhole bag (without any suction applied).

The bag was kept for gravity drainage below the patient's head level.

Before sealing the skin incision, body-temperature saline was poured into the subdural region to reduce pneumocephalus.

This parietal incision has closed first, and after filling the subdural space with warm saline, frontal incision is closed.

When treating patients of bilateral CSDH, the identical drain insertion technique was used on both sides.

Every patient received the typical post-operative treatment, including AED prophylaxis for 3 months.

Flat bed rest for 24 hours.

Removal of drain was done in 48 hours post-operatively in most cases, unless there was significant drainage.

A repeat CT scan was performed after removal of drain.

Additionally, we arranged for outpatient follow-up CT scans at three and six months.



Figure 1. Image showing tip of drainage catheter with exposed holes, across two burr holes placed subperiosteally.

Outcome measures (primary and secondary):

Primary outcome was based on recurrence within 6 months.

Secondary outcomes were incidence of re-operation and complications (both intra-operative and post-operative). When the mRS was 0-3, the clinical outcome was considered favourable, and when mRS was >=4, it was considered unfavourable.

Sample size

To calculate the sample size at 5% level of significance and 80% of power using the formula of $\mathbf{n} = (\mathbf{Z}_{\alpha/2} + \mathbf{Z}_{\beta})^{2*} \sigma^2 / \mathbf{E}^2$

Where,

n= Sample Size

 $Z_{\alpha/2}$ = Level of significance ($\alpha = 95\% = 1.96$)

 Z_{β} = Desired power (β =20%=0.84)

 σ = Standard deviation (σ =1.00)

E = Effect Size (E=0.45)

At 95% significance level with 80% power value, the minimum sample size would be 44.

Version 21.0 of the **SPSS** programme for Windows was used to analyse the data. We analysed ICU stay and Hospital stay, age, GCS by non-parametric Mann Whitney test. For sex, midline shift and co-morbidities the Chi-Square test were used. We used the Mann Whitney test to make a comparison of the GOS across the 2 types of brain surgeries at the time of discharge, at 1 month, at 3 months, at 6 months. Chi-Square test is used to study mRS across SDD and SPD, hematoma density appearance in CT scan across SDD and SPD, hematoma thickness across SDD and SPD and clinical outcome across SDD and SPD. At a level of significance that was supposed to P < 0.05.

Ethical clearance obtained from Institutional Ethical Committee and Scientific Research Committee.

Results

Patient Selection

During the study period, total 44 cases were studied. Cases were distributed according to the computer-generated random numbers for the insertion of subdural drainage or subperiosteal drainage after burr hole evacuation for chronic subdural hematoma. Total 22 cases (n=22) were allotted in each group.

A class I evidence for lower recurrence rate with after a burr-hole, twist drill, or craniotomy, the installation of a closed drainage system was reported by Santarius et al. in 2009 [6].

Although various types of drains have been used, as reported in literature, there is no consensus in superiority of any particular type of drain so far. We performed a prospective comparative study

of sub-periosteal drain versus sub-dural drain following burr-hole craniostomy.

Discussion

CSDH is clinically defined as hematoma presenting commonly after a few weeks following trauma, resulting in the observation of dark crimson liquid blood encircled by a thin capsular membrane after surgery. CSDH is one of the most common clinical entities treated surgically in neurosurgery. It is more prevalent in geriatric population. The reported incidence [1] is 19 per 1,00,000 populations. Recurrence rates are high and range between 5 to 30 %.

Markwalder [10] has given a clinical grading scale to support the impartial evaluation of patients who arrive with CSDH. It is applied both before and after surgery to evaluate the patient's clinical score. Nakaguchi [11] has classified the radiological appearance of CSDH into four main types: Homogenous, Laminar, Separated and Trabeculated type.

Level I evidence indicates that burr hole evacuation combined with postoperative drain placement is the standard recommended and most commonly utilized method of treating CSDH, and can greatly reduce recurrence rate.

In a study comparing above three techniques, it has been shown that compared to the burr-hole and twist drill craniostomy groups, the craniotomy group had the highest death rate and the worst results. The treatment of CSDH by burr-hole craniostomy is widely accepted method of treatment because, in comparison to twist drill craniostomy and craniotomy, it better balances a low recurrence rate against morbidity and death.

Santarius et al. 2009 [6], in their double burr-hole craniostomy randomised

controlled trial, they found that patients treated with subdural drain implantation significant improvement had a recurrence, mortality, and clinical prognosis at discharge. The implementation of closed-system drainage as a gold standard in the surgical management of CSDH with burr-hole craniostomy was only recommended in this one study (Type A recommendation). A recent meta-analysis conducted by Almenawar et al. (2014) [12] strengthens the function of the closedsystem drain implantation, which has been shown to dramatically lower the recurrence rate of hematomas.

A less invasive technique of placing a sub-periosteal (sub-galeal) drain was advocated by Gazerri [7] and Zumofen [8]. Both reported similar results in terms of problems and recurrence in contrast to the implantation of subperiosteal and subdural drain. When international survey on practice among neurosurgeons worldwide done, the discrepancy was reported. 50% preferred SDD and 27% preferred SPD. There was notable difference among our institute's surgeons. There are few recent researches comparing the efficacy of SDD and SPD but there are very few well designated randomized controlled trials. Seizure rates in patients treated with CSDH is between 2.3% to 5%. Higher incidence is seen in unilateral and mixed density CSDH. Prophylactic AED is suggested in most studies but few found that there was no discernible change in the frequency of seizures with prophylactic administration of AED and determined that the illness with AED far outweigh the advantages.

Zhang et al. (2019) [13] conducted a multicentre retrospective study on clinical results of burr hole evacuation for chronic subdural hematoma in comparison to subperiosteal drain. Recurrence was

comparable between the subdural (13.1%) and subperiosteal (11.2%) drain groups (p=0.502). Using a 6-month modified Rankin Scale, no statistically significant differences were seen between the groups (p=0.188),30-day mortality (mRS) (p=0.957), infection of the central nervous system after surgery (p=0.393), and length of hospital stay (p=0.231). Notably, two clinically significant cases of iatrogenic acute subdural hematoma (ASDH) occurred during removal of subdural drain. Both cases required reoperation and there was one death (50%), 45 days after surgery. They concluded that although clinical outcomes of subdural and subperiosteal drains are comparable, they cautioned against the use of subdural drains due to a clinically significant risk of iatrogenic ASDH during drain removal.

Soleman et al. (2019) [14] conducted a multicentre, patients receiving burr-hole drainage for CSDH were analysed in a prospective, randomised, controlled, and noninferiority Compared to the SDD group (12.00%, 95%) CI 6.66-19.73), the SPD group had a reduced recurrence rate (8.33%, 95% CI 4.28-14.72), and the treatment difference (3.67%, 95% CI -12.6-5.3) did not fulfil specified noninferiority criteria. By placing drains, the SPD group demonstrated noticeably lower rates of iatrogenic morbidity (P = .0184) and surgical infections (P = .0406). Both groups' length of stay and death rates were similar. They have come to the conclusion that SPD implantation reduced the rates of surgical infections, recurrences, and drain misplacements even if the noninferiority criteria were not satisfied. These results imply that SPD might be the preferred option in standard clinical settings.

Chih et al. (2019) [15] conducted a In order to directly compare patients getting SPD versus SDD drain installation for the treatment of CSDH, a prospective interventional trial was conducted. They found when compared to the SDD approach, SPD placement was just as effective and generally resulted in a reduced risk of surgical problems.

Glancz et al. (2018) [16] carried out a subgroup study of an earlier report that from a UK multicentre, CSDH patients participated in a prospective cohort research conducted from May 2013 to January 2014. They analysed information on the location (subdural or subgaleal), orientation (via a frontal or parietal burr hole), and length of insertion of the drain in relation to the results of patients older than 16 years who are having primary CSDH burr-hole drained. They concluded that After CSDH drainage, drain insertion is crucial, although the duration (1 or 2 days) and site (subgaleal or subdural) did not seem to affect clinical results or the rate of recurrence. Similarly, results where both frontal and parietal burr holes were created were unaffected by the placement of the drain.

AbdelFatah [17] conducted a review conducted in the past on patients who had CSDH evacuation between August 2012 and August 2016. No evidence of recurrence was there within 12 months. Twelve months after surgery, there was no death rate. Using two large burr holes, irrigation, and a sub-galeal Redivac low-pressure suction drainage, he found that surgical care of unilateral diffuse CSDH in adult patients was successful and did not result in recurrence.

Yadav et al. (2016) [18] studies the role of sub-galeal placing a suction drain for the clearance of a persistent subdural

hematoma. They prospectively studied 260 patients of CSDH treated with burr hole irrigation with (140 patients) or without (120 patients) suction drain. They concluded that sub-galeal the management of CSDH was made safe, easy, and efficient by closed suction drainage. In the group using suction drains, the recurrence rate was minimal.

A non-randomized prospective study by Chih et al. [15] including 30 symptomatic CSDH patients observed no statistically significant difference in patient characteristics, mean hematoma size, concomitant conditions, or pre-operative symptoms between the two groups when comparing the efficacy of SPD and SDD. They found that SPD placement was equally effective but marginally lower complications due to minor invasiveness of the SPD involving no contact with brain parenchyma. This difference however did not get a significant statistical level.

Kaliaperumal et al. [19] in a prospective randomized study, comprising 25 symptomatic CSDH patients each arm, found significantly better modified Rankin score after 6 months in the patients treated with SPD. They showed no recurrence in both groups. They also highlighted the risk of brain parenchymal injury in SDD.

Soleman et al. (2019) [14] in a large multicentre, prospective randomized controlled trial, comprising 220 patients compared 120 SPD versus 100 SDD. They found lower recurrence rate in SPD group (8.33%, 95% confidence interval 4.28-14.72) than in SDD group (12.00%, 95% confidence interval 6.66 – 19.73). Also, there was significantly decreased rate of post-operative drain placement resulted in infections (P = 0.0406) and iatrogenic morbidity (P = 0.0184). The SDD group's misplaced drain rate reached up to 17%;

their method of drain insertion may have contributed to this. They inserted the SDD from anterior to posterior burr holes.

Jetjumnong et. al. (2021) [20] conducted a prospective randomized study of 42 patients, 21 patients in each arm of SDD and SPD. Their data suggested that post-operative residual hematoma and midline shift that persist at 48 hours do not necessitate re-operation and had no effect on final outcome. Majority had complete resolution in 3 months and 6 months.

Summary and Conclusion

CSDH is one of the most common neurological entities treated surgically. It is more prevalent in geriatric population. The reported incidence [1] is 19 per 1,00,000 populations. Recurrence rates are high and range between 5 to 30 %. Burr-hole craniostomy and closed system drainage are used widely worldwide in treating symptomatic CSDH. There is no consensus of number of burr hole/s, use or irrigation, site of the drain whether subdural or subperiosteal, duration of drainage. We conducted a single centre prospective observational study comparing the results of subdural versus subperiosteal drain. Our study's primary objectives were to compare the effectiveness of subperiosteal and subdural drains and assess any variations in functional outcomes when treating symptomatic CSDH. Our objective was to assess the general demographics, to compare the neurological outcome based on mRS and GOS, to compare pre- and postoperative hematoma thickness, appearance, midline shift.

We studied 44 patients. SDD or SPD was inserted after burr hole drainage of symptomatic CSDH, selection being done on the basis of computer-generated random numbers: odd-number for SDD and

even number for SPD. This study was undertaken in Department of Neurosurgery of Medica Institute of Neurological Diseases (MIND) in Medica Superspecialty Hospital, Kolkata. The study design was interventional, prospective and comparative study in the Department of Neurosurgery. Patients included were those presenting to emergency or OPD with symptoms of CSDH and radiological confirmation, with or without evidence of mass effect and midline shift. Clotted SDH. asymptomatic patients, patients refusing surgery or those who were lost to follow up were excluded.

We did a prospective study design, and with the purpose to provide our single centre experience comparing the efficacy of two techniques, we intended to study a sample size of 44 patients (22 in each group) to demonstrate the difference in overall outcomes and rate of hematoma recurrence. Cases were distributed according to the computer-generated random numbers for the insertion of SDD or SPD after burr hole evacuation for CSDH. Total 22 cases (n = 22) were allotted in each group.

We did not find any statistically significant differences between SDD and SPD in terms of patient characteristics, associated co-morbidities (diabetes mellitus, hypertension, renal disorder, coagulopathies, heart diseases, history of trauma, history of brain surgery, GCS, mean hematoma size, clinical outcomes (as defined by mRS). There was also no statistical difference between SDD and SPD imaging characteristics (hematoma density appearance in CT scan), midline shift, complication rate, or recurrence rate. Favourable functional outcomes were determined by a GOS of 4 or higher at 3 months follow-up. Our study has shown

good outcomes in both groups at 3 months (mean GOS 4.73 in SPD and 4.77 in SDD) and 6 months (mean GOS 4.95 in SPD and 5 in SDD). P values of GOS at discharge, 1 month, 3 months and 6 months were 0.064, 0.39, 0.54 and 0.31; none of them were statistically significant. Our findings were consistent with previous studies comparing SDD and SPD.

Conclusion

Our study revealed that demography of SDD and SPD were comparable. Both SDD and SPD were safe equally effective and in treating symptomatic CSDH with no difference in final outcome. Complete radiological resolution of hematoma was observed in both SDD and SPD group at 6 months follow up. However, larger sample size and controlled study may be done in future for further analysis.

Data Availability

A data collection form was prepared to suit the proposed study. All relevant data were entered in it.

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Informed Consent

Informed consent was obtained from all patients or patients' relatives and approval for the study had already been taken from the Institutional Ethical Committee and Scientific Research Committee. A copy of the patient information sheet and the informed consent form were given to all the participants.

Conflict of Interest

The authors declares that the authors do not have conflict of interest

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Author Contribution

We confirm that this manuscript has been read and approved by all named authors. In addition, we declare that the manuscript is original and it is not being published or submitted for publication elsewhere.

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