Format

FOR SUBMITTING PG DISSERTATION PROPOSAL FOR CONSIDERATION INSTITUTIONAL RESEARCH COMMITTEE

SECTION- 1

PART A – GENERAL INFORMATION

Title of the dissertation : Effectiveness of single versus double burr hole for chronic subdural hematoma: A randomised controlled trial.

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Name of the course studying : M.Ch (Trauma Surgery and Critical care)

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Month and year of submitting dissertation : December 2024

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State whether it is intradepartmental or interdepartmental: (Encircle one option)

Intradepartmental / ~~Interdepartmental~~

If the study is Interdepartmental

State the names of collaborating departments-NA

State whether consent has been obtained from them: Yes

Total funds required for the study (in rupees): NA

Source of funding: NA

PART B – TECHNICAL DETAILS

Title of the dissertation : Effectiveness of single versus double burr hole for chronic subdural hematoma: A randomised controlled trial.

Introduction:

Problem statement: Chronic subdural hematoma (cSDH) is a common neurosurgical disorder and if not diagnosed and treated timely, may proven fatal. Incidence of cSDH are 1.72-13.1/1,000,000 population per year, and prevalent mostly in elderly persons[1]. cSDH can be traumatic or non-traumatic and need immediate attention irrespective of their etiology[2].There are three types of sub dural hematoma. Acute SDH(it occurs from 0-3 days), subacute(4-21 days) and chronic(occurs after 21 days) cSDH manifest with progressive neurological deficit.CSDH may have varied presentation ranging from simple headache to neurological deficit to drowsiness and coma.Clinical presentation along with radiological investigation helps in identifying cSDH. NCCT head is the investigation of choice.

Medical management has been advocated for old debilitating patient with cSDH included bed rest, steroids and mannitol but it needs prolonged hospitalization for these patients.[3]

The available surgical approaches include single burr hole, Double burr hole, craniotomy, and endoscopic burr hole.[4-6]

It is a common consensus that operative treatment would be more quickly, safely and effectively remove the mass [7]

Althogh the double burr hole has been the standard practice but new evidences have shown single burr hole is equally effective in dealing with chronic subdural haematoma. Most of the neurosurgeons prefer to place two burr holes on the side of lesion and irrigate through small silicon catheters to wash out the subdural space with or without use of sterile closed drainage system.[8] Few authors have suggested the use of a single burr hole and thorough irrigation for evacuation of cSDH.

Evacuation of cSDH by craniotomy is also indicated in certain situations and there are few surgeons who feel craniotomy has still a definite role in management of cSDH.In the light of current knowledge, there are various methods for surgical evacuation of cSDH. Described by different authors, all the methods have its merits and demerits. It is still debated that which is the best method for cSDH.

As new evidences and publication shows equal outcome compared with double burr hole, this study as a randomised control trial will help in understanding the effective of single vs double burr hole in cSDH.

Rationale: Althogh the double burr hole has been the standard practice but new evidences have shown single burr hole is also equally effective in dealing with chronic subdural haematoma. necessitates to compare outcome, mortality, morbidity between single Vs double burr hole craniotomy in cSDH.

Novelty: Despite extensive search, no published literature could be found on this topic in eastern region. This will be the first study in this geographical region conducted to compare single Vs double burr hole in cSDH patients.

Expected outcome: single burr hole are as effective as double burr hole in treatment of chronic subdural hematoma.

Application: Use of single burr hole in treatment of cSDH as single burr hole is a simple, less time consuming and less invasive treatment as it requires only one burr hole to be made.

Research question:

What are the benefits and risks involved in the use of single burr hole as compare to double burr hole in chronic subdural hematoma patients.

Research hypothesis: Single burr hole craniostomy as compare to double burr hole are equally effective and less risk in treatment of cSDH.

Aim and objectives:

Aim: To evaluate the efficacy of Single burr hole as compared to Double Burr Hole for chronic Subdural Hematoma.

Objective:

Primary-To determine the outcomes ,risks and benefits of single burr hole as compared to double burr hole in cSDH patients.

Secondary- To evaluate the morbidity, mortality, and associated complications in cSDH patients.

REVIEW OF LITERATURE

HISTORICAL PERSPECTIVE

Chronic subdural haematomas, first described by JJ Wepfer in 1656 [9], are common lesions that are easily treated with a minimum morbidity or mortality. As early as 1826, Bayle described pathophysiology of the CSDH as "chronic rebleeding", and in the 1850s, Ballarger and Heschl believed that CSDH evolved as the result of an inflammatory reaction in the subdural space [10,11]. Virchow in 1857 reported the same cases under the name of "pachymeningitis haemorrhagica interna" [12].

Yama-moto et al.[13] demonstrated that the irrigation with one burr hole is usually sufficient to wash out the hematoma in multiple cavities. They concluded that in most cases of cSDH, multiplicity did not mean multiple closed cavities and that all hematoma cavities were continuous with relatively wide routes of wide connection.

Nagakuchi et al.[14] demonstrated that the catheter tip located in the frontal showed better surgical outcome in one burr craniostomy with closed-system drainage and irrigation. The recurrence rates were 5% in frontal region, 38% in parietal region, 36% in occipital region and 33% at the temporal base.

In this study, all of patients with the tip of catheter in frontal region were not recurred. Among patients with one burr hole, only one of 5 patients with the tip of catheter in parietal region underwent recurrence. Kuroki et al.[15] have compared 'closed-system drainage with irrigation '(n = 45) with 'strict closed-system drainage' (n = 56) in cSDH managements, and found five recurrences in the former and one in the latter group. The result suggested that postoperative residual intracapsular air is a factor of recurrence which was statistically significant ($p < 0.05$). But, there is lack of general agreement as to what is the exact role of postoperative subdural air in the recurrence of cSDH.

Amir-jamshidi et al.[16] reported that the persistence of the posto- perative subdural cavity is a risk factor for reaccumulation of the hematoma and the presence of postoperative residual air prevents reduction of the cavity

Oishi et al.[17] demonstrated irrigation should be avoided to prevent complications caused by a sudden decrease in intracranial pressure and intraoperative invasion.

Taussky et al.[18] reported that patients operated on with one burr hole had a statistically significant higher rate of recurrence, wound infection and longer hospital stay. The theoretical explanation for higher recurrence rate of one burr craniostomy is following :

the residual hematoma fluid contains large concentrations of vasoactive cytokines, inflammatory mediator and fibrinolytic factors. The complete evacuation of hematoma seems to be directly linked to the success of surgical procedure. Thus, two burr hole is more efficient to flush out subdural fluid collection.

Amirjamshidi et al.[16] evaluated the role of GCS scores in the recurrence of cSDH. The results showed that GCS scores had a strong association with cSDH recurrence. Also, a study demonstrated significant correlations between GCS and CT scan findings in cSDH.

Lee et al.[19] reported that the duration of postoperative brain re-expansion was not only related with immediate brain re-expansion or pulsation during operation, but also preoperative GCS score.The width of a hematoma is usually determined at the level of its maximum thickness and has been reported to be correlated with patient age. This result is attributed to the brain atrophy associated with aging, which provides the hematoma with space in which to grow.

Yamamoto et al.[13] and Kang et al.[20] demonstrated that larger hematomas had a greater tendency to recur because postoperative subdural space was larger than that found after removal of a small hematoma.

Kang et al.[20] evaluated 302 patients with CSDH. Among the recurrent group, the one with a width greater than 2 cm was significantly higher than that of below 2 cm ($p < 0.05$). However, in agreement with a previous reports2,19), hematoma thickness on the preopera- tive imaging studies were found not to affect postoperative recurrence rate significantly in this study.

Suzuki and Takaku et al.[21] reported that osmotherapy performed using 20% mannitol was effective in preventing repeated bleeding of a cSDH. In the same fashion, the blood of patients with DM has a high osmotic pressure and increased platelet aggregation and this suggests that DM may contribute to decrease the rebleeding tendency of a cSDH and the recurrence of cSDH.

Methodology:

Study design:

Randomized control trial.
Single centre,
Non-inferiority trial,
Open label (blinding not permissible)

Study population:

Patients having chronic sub dural hematoma getting admitted in the Department of Trauma Surgery & Critical Care, AIIMS Patna.

Study participants:

(I) Inclusion criteria: All symptomatic patients of chronic sub dural hematoma selected for surgery

(II) Exclusion criteria:

1. Patients with recurrent cSDH
2. Asymptomatic cSDH
3. Patients with hematological disorder/anticoagulant drug use.
4. Patients with Septated membrane in cSDH
5. Acute on chronic SDH

Sampling:

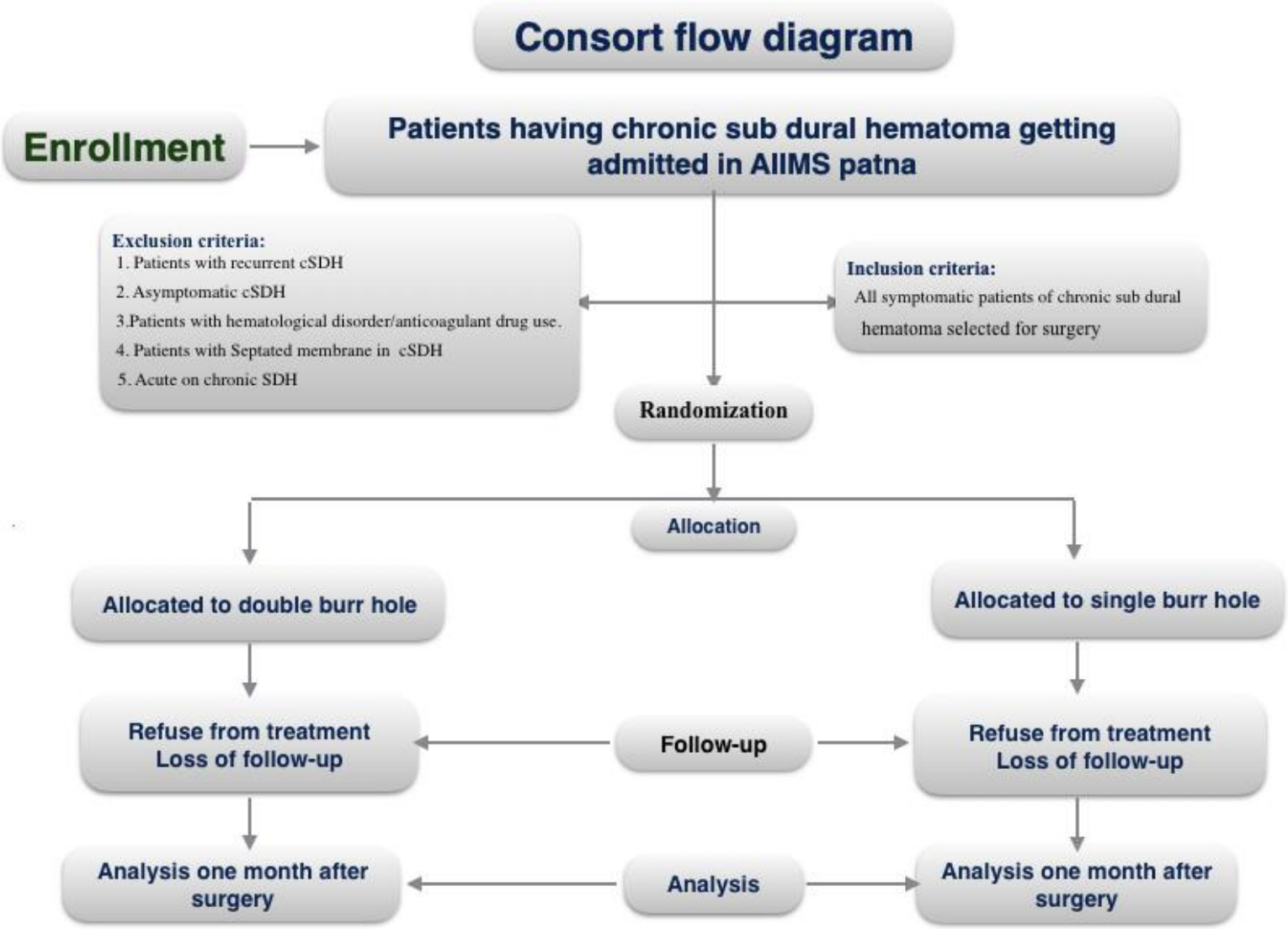
Sampling method:

Simple random sampling will be done using resources provided by Statistical Applet available in the website-http://digitalfirst.bfwpub.com/stats_applet/asset/applet_index.html
Sample population will be divided into two groups
Group A- Patients undergoing double burr hole
Group B- Patients undergoing single burr hole

Sample size-

Based on the results of the article by KC et al., (Journal of College of Medical Sciences-Nepal, Vol-18, No 2, Apr-Jun 2022), 11% of the subjects in the DBHC taken as control group and 3% in the SBHC as test group (based on an odds ratio of 0.235 between the test and the reference group) would experience the outcome, the study would require a sample size of 45 for each group (i.e. a total sample size of 90, assuming equal group sizes), to achieve a power of 80% and a level of significance of 5%, for declaring that the SBHC is not inferior to the DBHC at a 5% margin of non-inferiority (assuming that a smaller proportion is desirable).

In other words, if you use DBHC and SBHC for 45 subjects in each group, and 11% and 3% of the subjects in the DBHC as control and the SBHC as test group experiences the outcome, respectively, you would have 80% power to declare that at the most 6% (= [0.11 - 0.05] × 100) of the subjects treated with the SBHC test group would experience the outcome in the population (assuming that a smaller proportion is desirable).


Consort flow diagram
Enrollment
Patients having chronic sub dural hematoma getting admitted in AIIMS patna
Exclusion criteria:
1. Patients with recurrent cSDH
2. Asymptomatic cSDH
3.Patients with hematological disorder/anticoagulant drug use.
4. Patients with Septated membrane in cSDH
5. Acute on chronic SDH
Inclusion criteria:
All symptomatic patients of chronic sub dural hematoma selected for surgery
Randomization
Allocation
Allocated to double burr hole
Allocated to single burr hole
Refuse from treatment
Loss of follow-up
Follow-up
Refuse from treatment
Loss of follow-up
Analysis one month after surgery
Analysis
Analysis one month after surgery

Randomization details:

1. Sequence generation will be done via simple randomization.
2. Group allocation will be done via the use of sealed paper envelopes to reduce allocation bias.

Study Procedure:

After approval from the Institutional Ethical committee, a prospective study will be conducted in the department of Trauma surgery and Critical Care, AIIMS Patna
To compare the, in hospital stay,ICU stay/ ventilator days, rate of infection , post operative complications, neurological improvement ,recurrence, morbidity, mortality.
All patients fulfilling the inclusion criteria who need operative intervention will be randomised in two groups

Group A- Double burr hole (Frontal and parietal).
Group B- Single burr hole (Parietal)

Radiological assessment (NCCT BRAIN) will be done preoperatively, postoperatively at 6 hour and at time of discharge .
Patient will be followed up at an interval of one week, one month post discharge.
Follow up questionnaire (persistent of headache, focal neurological deficit, seizure and altered level of consciousness) will be filled in the master chart and evaluated further.

Data collection methods:

- A Detailed patients performa will be filled along with informed consent form.
- The data will be made in an excel sheet paper and master chart will be prepared at the end of study.
- Analysis will be done using statistical package for social sciences(SPSS) version22.0
- Proportions will be calculated for qualitative data and mean with SD for quantitative data.
- Chi square test will be applied for comparing categorical data.
- A probability value (P-value) < 0.05 will be considered statistically significant.
- Result will either be tabulated or represented graphically wherever necessary
- Study period- 12 months

If the clinical trial, whether registration with CTRI will be done: yes

Are the drugs/devices to be used approved for these indications by Drug Controller General of India (DCG-I)? (Enclose the approval letter for the drug/device from DCG-I for trial on humans or give undertaking to get the approval from DCGI; For all drugs and devices submit documents showing DCGI approval for the proposed indication of the study): NA

List of variables and their measurement methods with standardization techniques:

Independent variables: patients compliance

Outcome variables:

1. History of trauma,
2. Glasgow coma scale at the time of admission,
3. Interval between head injury (when history of trauma present) and surgery,
4. CT findings (Hematoma volume and density, mid line shift),
5. Systemic co-morbidity

Confounding and interacting variables: NA

Limitation of study:

This study is single center study.

Open non blinded trial

Benefits of the study:

The study will help contribute to standardization of treatment as Single Burr Hole is a simple, less time consuming and less invasive treatment.

Budget: NA

Questionnaires : NA

Consent form (English and Hindi version) Attached- Yes

Other relevant papers: Yes

Undertaking for DCGI approval: NA

Relevant references for the project:

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