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Quality control following change of drainage technique of chronic subdural hematomas at Universitetssykehuset Nord-Norge

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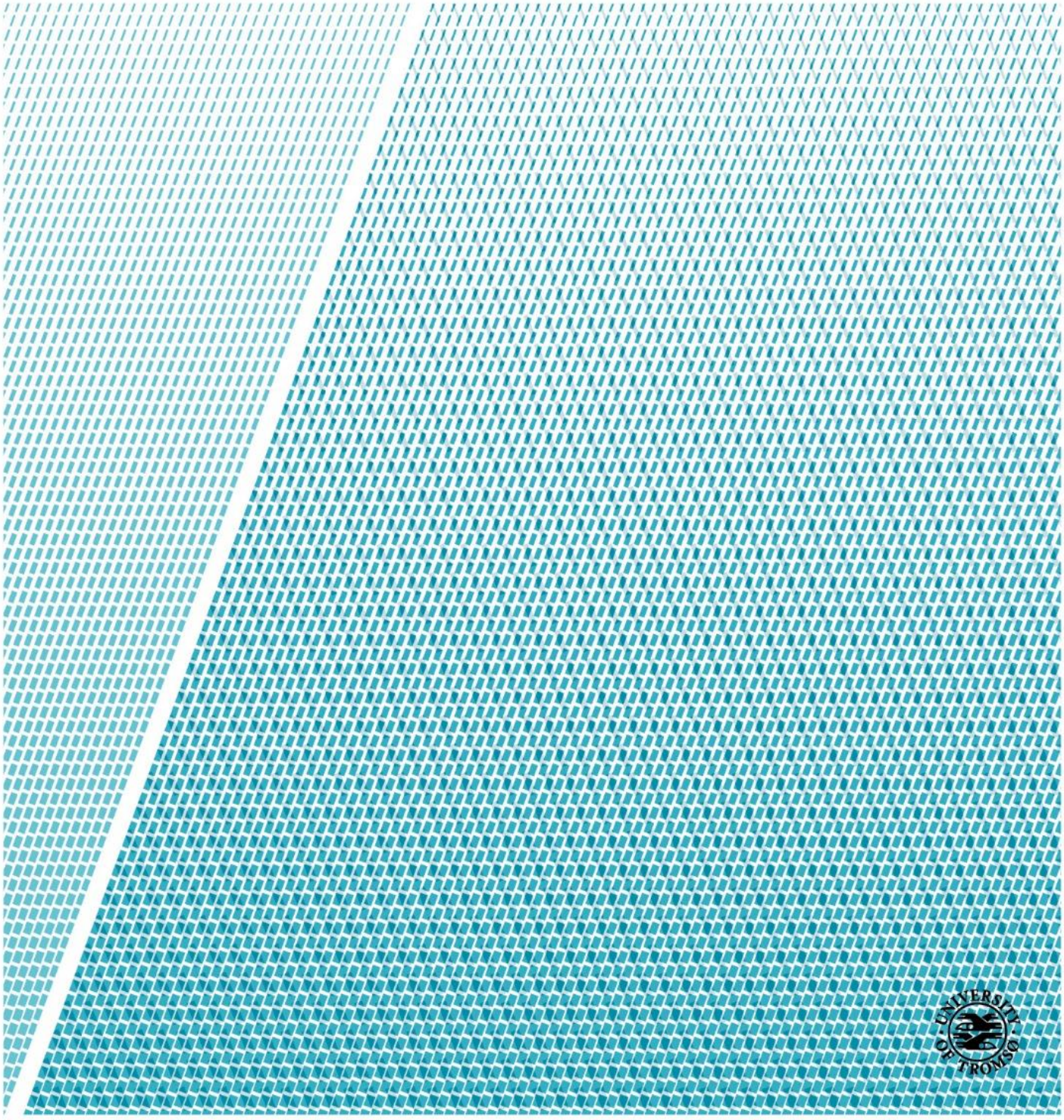

Preface

This study is conducted as a quality control after changing drainage technique on chronic subdural patients in march 2016. The study is largely based on the works of Sjåvik, Bartek et. al and their work comparing the different drainage techniques on patients with cSDH. There was no financial funding in this study. I would like to thank my mentors dr. Jørgen G. Isaksen and dr. Kristin Sjåvik for helping me with this thesis. While I have done all of the data gathering, statistical analysis and writing, their help was largely with the planning of the thesis and interpretation of the results.

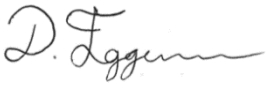

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Table of content

Abstract

Objective:

Chronic subdural hematoma is one of the most common neurosurgical conditions affecting the elderly. In March 2016 there was a change in drainage technique at the neurosurgical department, UNN, Norway from a continuous irrigation system to an active drain. This was following a multi-center study conducted by Sjåvik, Bartek, et.al showing fewer complications, with the same recurrence rate as continuous irrigation with an active-drain system. The active drain system is also less resource demanding. The main objective of this study was to compare the rates of recurrences of chronic subdural hematomas after this conversion. Complications, 30-day- and 90-day mortality were secondary end-points.

Methods:

Patients suffering from cSDH treated with burr-hole evacuation between March 2016 and September 2019 at UNN were included in this study. Patients were identified using the procedure code AAD10. 149 patients were included in the study, making up group A. Patients operated between January 2005 to December 2010 made up group B. These two groups were then compared in terms of baseline characteristics, and primary- and secondary outcomes.

Results:

Recurrence rate in group A was 16 (10.7%), and 18 in group B (10.8%) (p=0.976). In terms of secondary end-points group A had fewer complications (8.1%) than group B (14.5%) (p=0.074). 30-day mortality were the same between the groups (p=0.862). There was no difference between the groups in 90-day mortality (p=0.151).

Conclusions:

We found no difference in rates of recurrence after conversion to an active-drain system in march 2016. There was a clear tendency of fewer complications in group A, but no statistical significance. 30-day and 90-day mortality was the same between the two groups. Even though the study found no significant difference in primary-, or secondary-end points, the active-drain system is a technique requiring considerably less resources, while also showing a tendency of less complications.

Glossary and abbreviations

UNN: University Hospital of North Norway

cSDH: Chronic Subdural Hematoma

AD: Active drain

PD: Passive Drain

CID: Continous irrigation drain

GCS: Glasgow Coma Scale

CT: Computer tomography

SPSS: Statistical Product Service Solution

ICU: Intensive Care Unit

REK: Regional Ethical Committee

Introduction

Chronic subdural hematoma (cSDH) is a common neurosurgical condition primarily affecting the elderly. Yearly incidence have been reported to be ranging from 13.5 to 20.6 per 100.000 per year, but reaching up to 58.1 in patients over 65 years of age and is expected to keep increasing (1-3). cSDH is a slow-growing hemorrhage occurring in the subdural space. Compared to the acute subdural bleeding, cSDH has a less acute picture developing over days and weeks, usually caused by a minor head trauma, often not recalled by the patient. The clinical presentation varies from almost no symptoms to hemiparesis, headache, aphasia, confusion, parkinsonism and more. Due to cSDH presenting in a heterogenic matter, it is an important diagnosis to keep in mind, especially with old patients, patients on anticoagulative treatment or patients with a history of alcohol abuse presenting with neurological, cognitive or psychological symptoms. Chronic subdural hematoma is a differential diagnosis to stroke, and importantly dementia (4-6). Radiology is the established way of diagnosing cSDH, with CT being the recommended modality. Chronic subdural hematoma will often present itself as a hypodense lesion, but isodense and hyperdense lesions also occur (6).

Aging of the population and increased use of anti-platelet and anticoagulation are suggested to be the main drivers of the increasing incidence of cSDH, and it is expected to keep increasing in the future (4). While research has been conducted to evaluate the effect of medical treatment of cSDH, the established treatment is surgical evacuation of the hematoma (6). There are commonly three different ways to do this. Burr-hole evacuation, twist-drill craniostomy and craniotomy, of which burr-hole evacuation is the established method most often used in uncomplicated cases being less invasive than the craniotomy, while still being able to evacuate most hematomas effectively. There are different burr-hole techniques, most often applied with either one or two burr-holes. Twist-drill craniostomy is the least invasive technique, but requires the hematoma to be almost completely liquified in order to be effective. Craniotomy exposes the biggest part of the brain and is the most invasive method but is still often used in calcified and solid hematomas (5, 6). This is an area of continuing debate and research.

A challenge with cSDH is the recurrence of the hematoma and several studies have been conducted to better understand and find ways of preventing this. Recurrence rates have

shown to be ranging from 0-76%, though in reality it is believed to be closer to the region of 10-20% (6). The pathophysiology behind the expansion and recurrence of cSDH is believed to be complex, involving local inflammatory factors in the hematoma, and angiogenesis of fragile vessels in the outer membrane of the hematoma among other factors (6, 7). The dural border cell layer is believed to have an important pathophysiological role in the formation of the cSDH. The dural border cell layer lies between the dura mater and the arachnoid mater. Splitting of this cell layer results in an inflammatory process aimed at repairing the injury which often will resorb the hematoma. In the elderly patient, atrophy of the brain causes this layer to easier split due to stretching of the bridging veins passing in this area. In some cases there will be a membrane formation with a thicker outer layer, and a thinner inner layer incapsulating the hematoma. Within these membranes neovascularization of fenestrated, fragile vessels lacking tight junctions occur. Exudate leakage from these vessels in turn reinforces the inflammatory process driving the same process forward and expanding the hematoma (6, 7). This is thought to be part of the explanation of why a considerable share of patients with cSDH experience a recurrence of the hematoma and relapse in symptoms after treatment often ending in re-surgery.

A study by Santarius et. al (8) found significantly lower rates of recurrence when a passive drain (PD) was placed in the subdural space after surgical evacuation. In light of this study other drainage techniques have been applied (9 -13) including continuous irrigation drainage (CID) in the subdural-space (9). The rationale behind this is believed to be a better evacuation of the remaining blood products with a better brain re-expansion and less likelihood of hematoma recurrence. In the last few years a variation of this increasing in popularity is placing the drain in the subgaleal space. In a study by Gazzeri et. al (11), they showed the subgaleal drain to be an effective alternative, while being less invasive than the subdural drains. Zumofen et al (12) also conducted a study placing a passive drain in the subgaleal space with the argument that by placing the drain extracranially you avoid possible contact between the drain and intracranial structures, while at the same time being an easier, more cost-efficient procedure.

Following this a study performed at the Universitety Hospital of North-Norway (UNN) together with St. Olavs Hospital in Trondheim and Karolinska Institute in Sweden three different drainage techniques were compared in a comparative parallel cohort study. The three different techniques were CID in the subdural space, AD in the subgaleal space and

PD in the subdural space. The AD group and the CID group yielded comparable lower recurrence rates than the PD group. AD had a significantly lower complication rate, while also being a less demanding drainage technique in terms of equipment, operation time and postoperative observation than the CID and was therefore implemented at UNN, replacing the CID in march of 2016 (13).

The aim of this study was to evaluate results at UNN after changing to an active drain-system from a continuous irrigation drainage-system in March 2016. The main objective of the study was to look at rates of recurrence demanding repeat-surgery, while secondary end-points were complications, 30-day mortality and 90-day mortality.

Method

This was a comparative retrospective study, comparing the results of patients treated with CID and AD at UNN. We were looking to compare the patient population from between January 2005 to December 2010 (group B) against the patient population between March 2016 to september 2019 (Group A). All of the patient data has been gathered from the patient administrative database (DIPS). Patients operated with the burr-hole technique followed by placement of an active drain in the period after March 2016 until September 2019 at UNN were included in this study constituting group A. Group B data were used from an existing database in the Sjåvik study (13). In that study patients not treated according to policy were also included. Some patients were still treated with CID after March 2016, these were therefore included to make the two groups more comparable. Cases were identified in DIPS using the procedure code for evacuation of cSDH (AAD 10), case assertment procedures and data collection was done by manual review of the patient journal. Patients operated with craniotomy were excluded in both groups.

149 patients were identified and eligible for this study in group A, 166 patients in group B. Registered variables were demographics, level of independence, comorbidities, pre-operative symptoms, antiplatelet and anticoagulative medications, operation method, reoperation and post-operative complications. We defined a recurrence as a radiological finding together with clinical symptoms on the same side as the original cSDH occurring within six months of the operation needing reoperation, this is the same definition used by Sjåvik et al (13). The reasoning for choosing these variables were to ensure matching of the groups as well as possible with the study population used in the Sjåvik study (13)

(group B).

The primary end point was the rate of recurrence, and if this rate was statistically different from the rate before changing drainage method. In addition to recurrence of the cSDH, we also looked at secondary end-points in the form of complications such as intracranial infections, hemorrhages demanding the need to convert to craniotomy in the peri-operative period, pneumocephalus, acquired epilepsy, medical complications and other forms of intracranial hemorrhage. The complications were graded using the Landriel Ibañez classification scale for neurosurgical complications graded between I-IV. Grade I indicating any deviation from a normal postoperative course not requiring intervention, grade II indicating complications in need of intervention, grade III complications requiring admission to an ICU and grade IV indicating postoperative complication ending in death (14). Lastly we analyzed 30-day mortality and 90-day mortality.

Firstly we compared the baseline data to make sure the two groups were comparable. We then compared the primary and secondary end-points to see if there was a statistical significant difference between the two groups. Categorical data were compared using a Pearsons Chi-Square test. Numerical data were compared using an independent t-test. Significance level was set to $p < 0.05$ on all tests. All statistical analysis were performed in Statistical Product Service Solutions software (SPSS).

As this was a study ensuring best treatment, approval from the regional ethical committee (REK) was not necessary. This thesis required no interventions, examinations or contact with patients after treatment ended and therefore placed no further stress on the patients. The study was approved by data protection officials.

Results

Baseline characteristics between the two groups had some differences in terms of age ($p=0.013$) and level of independence ($p=0.035$), showing a younger and more independent population in group B. Male percentage, antiplatelet therapy, GCS, anticoagulant therapy and presenting symptoms were fairly equal and did not represent a statistical difference between the two groups. Baseline characteristics are presented in table 1.

Table 1 – baseline characteristics with p-values

Variable	Group A	Group B	p Value
No. of patients	149	166	
Age mean (SD)	76 years (10)	73 years (11)	p=0.013
Males	98 (65.8%)	111 (66.9%)	p=0.837
Antiplatelet therapy	62 (41.6%)	52 (31.5%)	p=0.058
Anticoagulant therapy	26 (17.4%)	39 (23.6%)	p=0.186
Presenting symptoms			
Paresis	70 (47.0%)	89 (53.6%)	p=0.240
Dysphasia	38 (25.5%)	52 (31.3%)	p=0.253
Headache	71 (47.7%)	80 (48.2%)	p=0.923
Vomiting	8 (5.4%)	12 (7.2%)	p=0.499
Glasgow Coma Scale			
13-15	129 (86.6%)	142 (85.5%)	p=0.791
9-12	13 (8.7%)	21 (12.7%)	p=0.262
3-8	6 (4.0%)	3 (1.8%)	p=0.238
Missing	1 (0.7%)	0 (0%)	p=0.290
Level of independence			
Independent	100 (67.1%)	129 (77.7%)	p=0.035
Home w/care	27 (18.1%)	17 (10.2%)	p=0.044
Nursing home	12 (8.0%)	20 (12.0%)	p=0.241
Missing	10 (6.7%)	0 (0%)	p=0.001

Table 1 *showing baseline characteristics of patients in group A (treated with an active drain) and group B (treated with a continuous irrigation drain).*

Primary End Point:

Of the 149 patients that qualified for this study in group A, 16 cases qualified as a recurrence (10.7%), compared to the CID cohort of 166 patients where 18 patients qualified as a recurrence (10.8%). When run through a chi-square test this gives us a p-value of over 0.05

and does not represent a statistical difference between the two groups (p=0.976). Results presented in table 2 and table 5.

Table 2 – frequency of cSDH recurrence

		Recurrence		
		Yes	No	Total
Group	A	16 (10.9%)	133	149
	B	18 (10.8%)	148	166
Total		31	282	313

Table 2 *showing fequenzy of cSDH recurrence in group A (treated with an active drain) and group B (treated with a continous irrigation drain).*

Secondary End Points:

12 patients in group A had complications (8.1%) compared to 24 (14.5%) in the CID cohort (group B). When put through a crosstabulation with Pearson chi square it does not represent a statistical significant difference between the two groups, giving us a significance of p=0.074, seen in table 3 and table 5. We also compared the difference between the two groups regarding complications graded two or worse on the Ibanez classification scale, indicating moderate to severe complications, showing no statistical differences between the groups p=0.420, presented in table 4 and 5. 30-day mortality was 4 (2.7%) in group A and 5 in group B (3.0%) (p=0.862). 90-day mortality was 4 (2.7%) in group A and 10 (6.0%) in group B (p=0.151). Primary-, and secondary end-points are summarized in table 5.

Table 3 – frequency of complications

		Complication		
		Yes	No	Total
Group	A	12 (8.1%)	137	149
	B	24 (14.5%)	142	166
Total		35	278	313

Table 3 *showing frequency of complications in group A (patients tread with active drain) and group B (treated with a continous irrigation drain).*

Table 4 – frequency of moderate to severe complications

		Ibanez II-IV		
		Yes	No	Total
Group	A	6 (4.0%)	143	149
	B	10 (6.0%)	156	166
Total		16	297	313

Table 4 *showing frequency of moderate to severe complications in group A (patients treated with active drain) and group B (treated with a continuous irrigation drain).*

Table 5 – primary –, and secondary end-points with p-values

Variable	Group A	Group B	p-value
Recurrence	16 (10.7%)	18 (10.8%)	0.976
Complications	12 (8.1%)	24 (14.5%)	0.074
Ibanez II-IV	6 (4.0%)	10 (6.0%)	0.420
30-day survival	4 (2.7%)	5 (3.0%)	0.862
90-day survival	4 (2.7%)	10 (6.0%)	0.151

Table 5 *showing frequencies and p-values of primary- and secondary end-points when patients treated with an active drain (group A) were compared against patients treated with a continuous irrigation drain (group B) using Pearsons Chi-Square.*

Discussion

This comparative study between group A (active drain) and group B (continuous irrigation drain) shows that there were no statistical difference between the rate of recurrence. The two groups were similar in baseline characteristics, other than age and level of independence indicating a younger and more independent patient population in group B. The presenting symptoms and level of consciousness were also similar. Indication for re-surgery were the same with both clinical symptoms and radiological findings before deciding to re-operate (department policy). Recurrences in the groups were the same, 16 in group A (10.7%) compared to 18 (10.8%) in the CID group, indicating that the active drain is not inferior to CID, even when placed extracranially.

There were fewer complications in group A than in group B, showing a tendency of better results in group A, although not statistically significant. Even though there were not statistically any difference between the groups, the relative small sample sizes means there would have to be a considerable difference to get a p-value <0.05. There still seems to be a clear tendency towards better results with an active drain, especially when looking at complications, which is reinforced when looking at other studies with similar end-points (13,15). When looking at the severity of complications; group A had 6 (4.0%) patients with an Ibanez-score of 2-4, while group B had 10 (6.0%) possibly indicating more serious complications regarding CID. Based on the baseline characteristics we would expect group B to have less complications if the two treatments were equal. This study shows a tendency of fewer complications in the older and less independent group A. In group A one patient had an Ibanez-score of 4, meaning complication resulting in death. This patient was first treated with an active drain, but due to an acute recurrence of the cSDH he was operated again the same day, this time with CID. Post-operatively the patient falls to a GCS of 3 along with the outgoing drain stopping to produce blood and the ingoing drain was shut. CT caput showed fresh blood products around the drainage-system and an increase in the hygroma which was then attempted evacuated at the ward unsuccessfully. Due to the patients age and sick history treatment was stopped and the patient dies a week later. This particular case could be attributed to multiple explanations, one being that CID is a procedure associated with higher complication-rates in other studies (13, 15), but also the fact that when implementing another procedure, the replaced procedure gets done less, and it becomes harder to keep this skill at an adequate level.

Of particular concern is the fact that CID is based on infusion of fluid into the subdural space. This is done through an active drain, with a passive outgoing drain removing the irrigation fluid, blood products and improving brain re-expansion. A possible complication in a faulty outgoing drain will therefore potentially cause the treatment to acutely increase the intracerebral pressure of the patient, in worst case causing herniation. This is not an issue with the active drain, as there is no infusion of fluid into the patients intracranial space, making it in theory a safer alternative for draining the hematoma. Another complication of cSDH evacuation in general is an acute hemorrhage; the more invasive nature of the CID being placed into the subdural space could explain in part the higher frequency of complications reported in other studies (13, 15). By placing the drain in the subdural cavity you run the risk of an artificial object coming into contact with the subdural membrane or brain parenchyma

possibly causing irritation, infection, hemorrhage or direct damage to the brain (11-13). Although one earlier study done at UNN showed no increase in complications using CID versus passive drain (PD) or no drain (9). The active drain applied in this study on the other hand was placed between the skull and the scalp, in the subgaleal space (referred to as subperiosteal in some studies), thus making the active drain a less invasive technique, never coming into contact with intracranial structures and decreasing the chances of causing hemorrhage or deep brain infections, while at the same time being a technically easier method of applying a drain (12).

Even though we were not able to produce a statistical significant results, this study did show a tendency of better results with the active drain, especially in terms of complications, while not being inferior to CID in terms of recurrences. The use of an active drain is a less resource-demanding technique than CID. This includes a shorter operation time, less equipment needed and shorter observation time post-operatively, it is also as mentioned earlier a technically easier procedure than placement of a CID in the subdural cavity. We therefore believe that the use of an active drain is still preferable for the reasons above.

Limitations of this study include retrospective limitations and a small study sample. Due to a relative short time frame and a low population number the total number of operating cases were fairly low, making it harder to produce significant results. Because of minor differences in variable registration, comparison of raw data in SPSS became technically problematic. Summarized data from group B were therefore used in the statistical analysis.

Strengths of the study were that both study populations were treated and followed up at the same center. Operating theaters, indications for operating, operation teams and peri-operative routines were considered to be the same. Because of regional reference patterns in the Norwegian Health Care system, referral bias became a non-issue.

Conclusion

There were no differences between group A (treated with active drain) and group B (treated with continuous irrigation) in terms of rates of recurrence. There is a tendency of fewer complications in group A, than in group B, but there were no statistical significant difference between the two groups. 30-day mortality and 90-day mortality was the same between the two groups. In conclusion we did not find any significant difference between the two groups after converting to an active drain system in March 2016, but due to active drain requiring less

resources and being relatively less invasive it is still the preferred drainage method to treat cSDH.

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GRADE-articles

Referanse: Javadi A, Amirjamshidi A, Aran S, Hosseini SH. A randomized controlled trial comparing the outcome of burr-hole irrigation with and without drainage in the treatment of chronic subdural hematoma: A preliminary report. World neurosurg. 2011;75(5/6):731-36			Studiedesign: RCT **Grade - kvalitet** 2
Formål	**Materiale og metode**	**Resultater**	**Diskusjon/kommentarer/sjekkliste**
Compare recurrence rates and complication rates using burr-hole irrigation with and without drainage treating chronic subdural hematomas **Konklusjon** Surgical technique did not seem to be main variable in determining outcome. Patient factors seem more important. **Land** Tehran, Iran **År data innsamling** June 2007 to July 2009.	Fourty patients with chronic subdural hematomas were included in the period of June 2007 to July 2009. Patients assigned to burr-hole with drain (BI + D) or burr-hole without drain (BI – D). Inclusion: Patients with a GCS of less than 15, neurological deterioration, and hematoma volume of 30 ml with midline shift of over 5 mm were included. Exclusion: Patients with a calcified or organized hematoma, severe comorbidities, end-stage disease, secondary hematoma after shunting procedure, tumor infiltration or a history of previous craniotomy. Patients under age of 18. Patients randomized with balanced block method. Primary and secondary outcomes analyzed with Chi-squared-test	Recurrence rates: 1 month follow up: BI + D: 1 BI – D: 0 p-value 0.31 6 month follow up: BI + D: 0 BI –D: 1 P-value 1.00 Both patients were on antiplatelet therapy, and the one in the BI – D group also had diabetes. Mortality: Bi + D: 4 BI – D: 2 p-value: 0.37 Morbidity: Bi + D: 4 BI – D: 2 p-value: 0.37 These statistical data could be attributed to small sample size and low rates of recurrence in both groups. Both groups well matched.in base characteristics.	**Sjekkliste:** • **Er formålet klart formulert? Yes.** • **Hvem er inkludert/ekskludert?** (seleksjon/generaliserbarhet) • **Var gruppene like ved starten? Yes.** (selesksjon?, har randomiseringen fungert?) • **Randomiseringsprosedyre?** • **Ble deltakere/studiepersonell blindet mht gruppetilhørighet? Yes.** • **Ble gruppene behandlet likt utover «intervensjonen»? Yes.** • **Primære endepunktet – validert?** (Classificatin bias?) Yes. • **Ble deltakernne gjort rede for på slutten av studien?** (attrition/follow-up bias) • **Hva er resultatene? Presisjon?** • **Kan resultatene overføres til praksis? Yes.** • **Ble alle utfallsmål vurdert? Yes.** • **Er fordelene verdt ulemper/kostnader?** • **Annen litteratur som styrker resultatene? Most litterature show improved results with drain.** **Hva diskuterer forfatterne som:** **-styrke: Not discussed.** **-svakhet: Low sample size. Difficult with blinding in an operative setting.** **Har resultatene plausible forklaringer?**

Referanse: Gazzeri R, Galarza M, Neroni M, Canova A, Refice GM, Esposito S. Continuous subgaleal suction drainage for the treatment of chronic subdural hematoma. Acta neurochirurgica. 2007;149(5):487-93			**Studiedesign: Pasientserie** **Grade - kvalitet** 1/2
Formål	**Materiale og metode**	**Resultater**	**Diskusjon/kommentarer/sjekkliste**
A retrospective study to analyze recurrence-rates, morbidity and mortality after introducing a new drainage-technique in treating chronic subdural hematomas. **Konklusjon** ***Authors conclude that the insertion of a subgaleal drain was equally effective as other methods and is less invasive.*** **Land** Rome, Italy **År data innsamling** 2002-2005	**Inclusion: Patients in the period of January 2002 to December 2005 in the Neurosurgical department of Addolarata Hospital were treated with a burr-hole evacuation followed by a closed drainage system, placing a Jackson Pratt drain in the subgaleal space.** **Exclusion: Patients with an additional intracerebral- or epidural hematoma.** **Total number of patients 224. Mean age of 71.5 years. 146 were men, 88 were women. Fourteen patients had received anticoagulant therapy.**	Results of the study show a recurrence-rate of 7.5% , this is comparable to other studies using different drainage techniques. Mortality 0.8% Morbidity 1.3% No patients presented with symptomatic pneumocephalus. Postoperative complications showed in 3 patients. One with subgaleal empyema, 2 patients suffered motor seizures. 2 patients got pneumonia, treated succesfully with antibiotics. 2 patients died. 1 developing asdh hours after the operation. The other came to the hospital in a coma and died after 2 weeks having not shown any improvement post operatively.	**Sjekkliste:** • **Er formålet klart formulert? Yes.** • **Var studien basert på et tilfeldig utvalg fra en egnet pasientgruppe?** (selesksjons bias)* All patients between • **Var inklusjonskriteriene klart definert?*** • **Var alle pasientene i samme stadium av sykdommen?*** • **Var responseraten høy nok?* Frafallsanal.?** • **Ble det brukt objektive kriterier for å vurdere/validere endepunktene?** (Classifc. Bias) **Yes.** • **Ved sammenligninger av pasientserier, er seriene tilstrekkelig beskrevet?*** • **Er prognostiske/konfunderende faktorer beskrevet7tatt hensyn til i design/anal? No.** • **Var registreringen prospektiv? Nei.** • **Var oppfølgningen lang nok! Not discussed.** • **Var oppfølgningen tilstrekkelig for å nå endepunktene?** (attrition/follow-up bias) **Yes.** • **Stoler du på resultatene? Yes.** • **Kan resultatene overføres til praksis? Yes.** • **Annen litteratur som støtter resultatene? Yes.** **Hva diskuterer forfatterne som:** • **Styrke** • **Svakhet** • **Limitations and strengths of the study are not discussed in the paper.** Har resultatene plausible biologiske forklaringer? Yes.

Referanse: Santarius T, Kirkpatrick PJ, Ganesan D, Chia HL, Jalloh I, Smielewski P, et al. Use of drains versus no drains after burr-hole evacuation of chronic subdural haematoma: a randomised controlled trial. Lancet (London, England). 2009;374(9695):1067-73.			Studiedesign: RCT **Grade - kvalitet** 3
Formål	**Materiale og metode**	**Resultater**	**Diskusjon/kommentarer/sjekkliste**
Effect of drains on recurrence rates and clinical outcomes. **Konklusjon** Roughly half the recurrence rate with drain. Mortality lower at 6 months.Better functional status. Complication rates were the same between groups. **Land** UK **År data innsamling** November 2005 to November 2007.	Inclusion: Patients aged over 18 with csdh requiring surgery. Exclusion: Ipsilateral haematomas who had been treated within 6 months of presentation with a shunt for csf diversion, and for patients who needed other forms of surgery for their csdh. Randomized via block randomisation with a web-baes randomisation software. Patient group revealed to operator in a sealed envelope after deemed safe for patient to have drain inserted. Outcomes masked to clinicians when possible. Primary outcome: Recurrence rate Secondary outcome: Clinical outcome at discharge and at 6 months and length of hospital stay. Analyzed categorical data with a Chi-square test. Other outcomes depending on the variable-type.	Groups well matched. 0 lost to primary outcome follow-up. 31 lost to secondary follow up in drain-group. 20 lost to secondary follow-up in no-drain group. Recurrence: Drain: 9.3% No-drain: 24% 6 months mortality:: Drain: 8.6% No- rain: 24% Trial stopped early in nov 2007 because of the high efficacy of the drain. Deemed inappropriate to assign patients to «no-drain» group. Complication rates no statistical significant difference between the two groups. Weakness of study is that it is a single-centre study and some missing data.	**Sjekkliste:** • **Er formålet klart formulert? Yes** • **Hvem er inkludert/ekskludert?** (seleksjon/generaliserbarhet) • **Var gruppene like ved starten?** (selesksjon?, har randomiseringen fungert?) • **Randomiseringsprosedyre?** • **Ble deltakere/studiepersonell blindet mht gruppetilhørighet?** • **Ble gruppene behandlet likt utover «intervensjonen»?** • **Primære endepunktet – validert?** (Classificatin bias?) • **Ble deltakernne gjort rede for på slutten av studien?** (attrition/follow-up bias) • **Hva er resultatene? Presisjon?** • **Kan resultatene overføres til praksis? Yes** • **Ble alle utfallsmål vurdert?** • **Er fordelene verdt ulemper/kostnader?** • **Annen litteratur som styrker resultatene?** **Hva diskuterer forfatterne som:** **-styrke** **-svakhet** **Har resultatene plausible forklaringer? Yes.**

Referanse: Hennig R, Kloster R. Burr hole evacuation of chronic subdural hematomas followed by continuous inflow and outflow irrigation. Acta neurochirurgica. 1999; 141(2): 171-76.			Studiedesign: Non-randomized clinical trial **Grade – kvalitet** 2
Formål	**Materiale og metode**	**Resultater**	**Diskusjon/kommentarer/sjekkliste**
To compare CID against no drainage, passive drainage and crainotomi in regards of recurrence and complications in the form of empyema and death. **Konklusjon** CID yielded significantly better results in recurrence, and lower morbidity/mortality than group B, C and D. **Land** Norway **År data innsamling** 7 year period. What year they were collected are not adressed.	Inclusion criteria: cSDH with remaining cavity after surgery. Exclusion criteria: Complete brain-reexpansion after surgery. Haematoma after shun implantation. 137 patients included, 13 patients excluded over a period of seven years. 84 men and 54 women, aged between 27-90 years old. Median age men 70, women 73. Patients divided into four groups: A: Two burr-holes with continous irrigation B: Two burr-holes with no drainage C: Two burr holes with passive drainage D: Craniotomy	Recurrcence: Group A: 2.7% recurrence Group B: 32.6% recurrence Group C: 23.5% recurrence Group D: 44.4% recurrence CID group was significantly better than the other groups in term of recurrence (p=0.001) Morbididty in the form of empyema: Group A: 0% Group B: 5.3% Group C: 5.9% Group D: 0% Mortalitty: Group A: 0% Group B: 7.9% Group C: 11.8% Group D: 11.1% Baseline characteristics not compared between the groups. Before the randomized trial could start there was a test-period of three months with group A. The results were compared with the other groups and were so much better that a randomized trial was declinded and the operation method was changed.	**Sjekkliste:** • **Er formålet klart formulert? Yes.** • **Hvem er inkludert/ekskludert?** (seleksjon/generaliserbarhet) • **Var gruppene like ved starten?** (selesksjon?, har randomiseringen fungert?) **Groups are not compared in terms of baseline characteristics, no information on how the groups were divided.** • **Randomiseringsprosedyre?** • **Ble deltakere/studiepersonell blindet mht gruppetilhørighet? No.** • **Ble gruppene behandlet likt utover «intervensjonen»? Yes.** • **Primære endepunktet – validert?** (Classificatin bias?) Yes. • **Ble deltakernne gjort rede for på slutten av studien?** (attrition/follow-up bias) Yes • **Hva er resultatene? Presisjon?** • **Kan resultatene overføres til praksis? Yes.** • **Ble alle utfallsmål vurdert? Yes.** • **Er fordelene verdt ulemper/kostnader? Yes.** • **Annen litteratur som styrker resultatene? Yes.** **Hva diskuterer forfatterne som:** **-styrke: Strong results.** **-svakhet: Not discussed.** **Har resultatene plausible forklaringer? Yes.**

Referanse: Sjavik K, Bartek J, Jr., Sagberg LM, Henriksen ML, Gulati S, Stahl FL, et al. Assessment of drainage techniques for evacuation of chronic subdural hematoma: a consecutive population-based comparative cohort study. Journal of neurosurgery. 2017:1-7.			**Studiedesign: Prospektiv kohortestudie** Grade - kvalitet 2/3
Formål	Materiale og metode	**Resultater**	**Diskusjon/kommentarer/sjekkliste**
Comparing three different drainage techniques. Continious irrigation drainage, active drainage and passive drainage. Primary end-point: Recurrence rates Secondary end-point. Morbidity and mortality **Konklusjon** ***AD and CID superior to AD looking at primary end points. CID associated with higher complication rates. Mortality rates and overall survival similar between groups.*** **Land** Norway and Sweden **År data innsamling** 2005 to 2010.	**All patients undergoing evacuation of primary csdh in the period of January 1st 2005 to December 31st 2010 at the neurosurgical departments of Karolinska institut, the University Hospital of Northern Norway and St. Olavs University Hospital were included.** **Exclution: Patients who underwent any other form of intracranial operation in last 6 months, or csdh as a result of arachnoidal cysts.** **Total of 1260 patients.** **The categorical data were analysed using Chi-squared test. Comparisons of means were analysed using ANOVA statistics.**	Recurrence rates: CID: 15 of 147 (10.2%) PD: 66 of 330 (20.0%) AD: 85 of 764 (11.1%) Complications: CID: 14.5% PD: 7.3% AD: 8.1% Mortality 30 days: CID: 3% PD: 4.3% AD: 3.1% PD assosciated with a higher chance of recurrence than other two methods. CID associated with a higher chance of complication than the other two methods. No difference in mortality rates. Some differences in baseline characteristics. Sex, preoperative symptoms, and use of anticoagulants. Differences in outcomes prevailed following adjustment for baseline characteristics.	**Sjekkliste:** • Formålet klart formulert? **Yes** • Er gruppene rekruttert fra samme populasjon/befolkningsgruppe? (seleksjons bias) **Yes** • Var gruppene sammenliknbare i forhold til viktige bakgrunnsfaktorer? (seleksjons bias)* **Yes** • Var de eksponerte individene representative for en definert befolkningsgruppe/populasjon?* **Yes** • Ble eksposisjon og utfall målt likt og pålitelig (validert) i de to gruppene? (Classification bias) ** **Yes** • Er den som vurderte resultatene (endepunkt- ene) blindet for gruppetilhørighet?** **No** • Var studien prospektiv? **Yes** • Ble mange nok personer i kohorten fulgt opp? (Attrition bias/follow-up-bias) **Yes** • Er det utført frafallsanalyser? (Eval. attrition bias) **No** • Var oppfølgingstiden lang nok til å påvise positive og/eller negative utfall? **Yes** • Er det tatt hensyn til viktige konfunderende faktorer i design/ gjennomføring/analyser? **Yes** • Tror du på resultatene? **Yes** -Bradford Hills criteria (time sequence, dose-response gradient, biological plausibility, consistency….) • Kan resultatene overføres til den generelle befolkningen? **Yes** • Annen litteratur som styrker/svekker resultatene? **Yes, other studies support findings.** • Hva betyr resultatene for endring av praksis? **Led to a change in treatment of cSDH at UNN.** **Hva diskuterer forfatterne som:** • **Styrke: High compliance, few patients lost in follow-up. No refferal-bias due to referral patterns in Scandinavian Health Care system.** • **Svakhet: Possible detection bias in radiology. Different evacuation-strategies done at different hospitals with different operation teams could affect result.**