Minimal Access vs. Open Spine Surgery in Patients With Metastatic Spinal Cord Compression - A One-Center Randomized Controlled Trial

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Abstract. *Background/Aim:* We conducted a randomized controlled trial to investigate whether minimally access spine surgery (MASS) is less morbid than open surgery (OS) in patients with metastatic spinal cord compression (MSCC). *Patients and Methods:* A total of 49 MSCC patients were included in the trial. The outcome measures were bleeding (L), operation time (min), re-operations and prolonged wound healing. *Results:* The median age was 67 years (range=42-85 years) and 40% were men. The peri-operative blood loss in the MASS-group was significantly lower than that in the OS-group; 0.175L vs. 0.500L, ($p=0.002$). The median operation time for MASS was 142 min (range=72-203 min) vs. 103 (range=59-435 min) for OS ($p=0.001$). There was no significant difference between the two groups concerning revision surgery or delayed wound healing. *Conclusion:* The MASS technique in MSCC patients is associated with less blood loss, but a longer operation time when compared to the OS technique.

In recent years, an increasing number of cancer patients develop symptomatic metastatic spinal cord compression (MSCC). This is most likely a result of the advancement in cancer treatment and prolonged survival among cancer patients in general (1, 2). The optimal treatment for MSCC patients is considered to be surgery in combination with radiation therapy (3, 4). However,

the majority of patients are not recommended surgical treatment due to poor health and relatively short survival time, which means that they cannot withstand large surgical procedures (5, 6). Minimally access spine surgery (MASS) is considered less morbid than open surgery (OS), and results in fewer wound complications and less bleeding. The existing evidence for bleeding in minimal *versus* open surgery from observational studies is gathered in two recently published reviews by Pennington and colleagues and by Lu and colleagues. The conclusions were that "The overall quality of evidence currently available is low—all evidence is currently class III or IV" (7, 8). With this clinical trial we aimed to examine the perioperative bleeding, surgery time and number of revisions of MASS compared with conventional OS in the treatment of patients with MSCC. The hypothesis of the study was that MASS results in significantly less blood loss, shorter surgery time and fewer revisions when compared to open surgery.

Patients and Methods

Study population. The study includes MSCC patients admitted to Rigshospitalet, Denmark from January 1st, 2014 to January 1st, 2017. The hospital serves a population of 2.3 million people from the eastern part of Denmark. The MSCC diagnosis was based on magnetic resonance imaging (MRI) in combination with clinical symptoms such as back pain and/or neurological impairment. Patients with MSCC between T5 to L3 were included. Patients with Tokumashi score ≤ 4 , in need of sacral or iliosacral instrumentation, and patients who were candidates for a corpectomy were excluded.

All patients were included in the study at referral and information regarding age, sex, primary oncological diagnosis was registered. According to the hospital guidelines, the on-call oncologist examined all patients and the treatment strategy was decided within 24 h after admission.

Study design. This study is a non-blinded, randomized controlled, parallel-group trial, conducted as a single center study. Patients were randomly assigned (balanced 1:1) to either MASS or OS. A third-

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Key Words: Metastatic spinal cord compression, spinal surgery, spinal metastases, vertebral metastases, operation time, bleeding, minimal access surgery.

Figure 1. Flow of patients in the study.

party computer-generated list of random numbers and a fixed block size of 20 made the allocation sequencing. Informed consent was obtained from all individual patients. The allocation concealment was secured by using sealed, numbered envelopes. The envelopes were opened immediately after agreement with the patient. The patient, surgeon and staff members were non-blinded.

From previous studies including patients with spinal metastases from a wider range of primary cancers and based on patient files, it was calculated that the mean blood loss during open surgery was 1,500 ml (standard deviation 13.5 ml) (9, 10). A clinically relevant reduction in blood loss was considered to be 400 ml, corresponding to one unit of packed red blood cells. With a significance level of 5% and a power of 80% it was estimated that a total of 62 included patients would be necessary. The trial was closed when the prescheduled date of closure was reached. By then, a total of 2.5 blocks and 50 patients were included. The study was approved by the Danish National committee on Biomedical Research Ethics (Identifier: H-2-2011-050), and the study was preregistered at ClinicalTrials.gov (Identifier: NCT01865942). All procedures were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All participants provided informed consent.

Treatment procedure. All patients were operated with posterior pedicle screw instrumentation two levels above and two levels below the metastatic level. In the MASS-group, decompression was performed through a localized incision at the metastatic level. In the OS-group decompression was performed through a conventional

laminectomy. The decompression was done only posteriorly with decompression of the nerve roots. Any visible tumor mass was removed. Tumor mass was also removed if it compressed the neurologic structures. However, the goal was not to remove as much tumor mass as possible. During the operation, the surgeons took biopsies from the vertebra body and the dissected tumor. According to standard procedure, biopsies were sent for analysis for infection and pathology.

Clinical outcomes. The primary outcome was perioperative blood loss and secondary outcomes were operation time and complications (infections and instrumentation failures). Perioperative blood loss was measured as the volume in suction containers and as the weight of surgical sponges (1 g=1 ml). Operation time was measured from first incision to last suture. Infections and instrumentation failures were included as complications if revision surgery was needed. We also registered if there was delayed wound healing or mild infection that lead to postponed radiotherapy or chemotherapy treatment.

Statistical analyses. The MASS and OS groups were compared using independent *t*-test for continuous variables with a normal distribution and homogeneity of variances and Mann-Whitney test for continuous variables with a skewed distribution. The possible difference in survival between the two groups was estimated with Kaplan-Meier survival curves and multivariate Cox regression analysis including 95% confidence intervals (95%CI). A *p*-value <0.05 was considered statistically significant. Analyses were conducted using Stata 14 (StataCorp, College Station).

Table I. Baseline characteristics in the minimal access spine surgery (MASS) and the open surgery groups (OS).

Characteristics	MASS Group, n=23	OS group, n=26	p-Value ²
	Median (range) or Mean±SD or % ¹	Median (range) or Mean±SD or % ¹	
Age (years)	65.9 (range=49-85)	67.6 (range=42-88)	0.400
Gender	Male 38%	Male 43%	0.724
Primary site of cancer			0.384
Lung	3	6	
Breast	9	7	
Prostate	4	1	
Unidentified	4	1	
Renal	2	3	
Pancreatic	1	0	
Melanoma	0	1	
Thyroid	0	1	
Lymphoma	3	0	
Other	0	3	
2017 Revised Tokuhashi score (28)	8.0 (range=4-12)	7.6 (range=3-12)	0.650
0-5	4	4	
6-9	10	11	
10-12	8	8	
Spinal level of the metastasis decompressed during surgery			
TH 5-8	6	7	0.236
TH 9-12	11	10	
L 1-3	9	6	

¹Values are percentages for categorical variables, means (SD) for continuous variables with a normal distribution, or medians (range) for continuous variables with a skewed distribution; ²p-value comparing the MASS and the OS group, assessed using independent *t*-test for continuous variables with a normal distribution and homogeneity of variances, Mann-Whitney test for continuous variables with a skewed distribution and chi-square tests for categorical variables.

Results

A total of 53 patients were offered to be part of the study (Figure 1) and 50 agreed to participate. A total of 27 were randomized in the MASS group and 23 in the OS group. One patient in the MASS group was excluded because the biopsies showed that the patient suffered from a chronic infection instead of cancer. All included patients were operated, and none were lost to follow-up.

There was no significant difference between the MASS- and the OS-group regarding sex, age, 2005 Revised Tokuhashi Score or primary tumor diagnosis (Table I).

The MASS technique resulted in significantly lower blood loss and a significantly longer operation time when compared to the OS technique (Table II). The median blood loss in the MASS group was 0.175 l (range=0.03-0.80 l) versus 0.500 (range=0.100-2.00 l) in the OS group. The median operation time in the MASS group was 142 min (range=72-203 min) versus 103 min (range=59-435 min) in the OS group. The number of reoperations were the same, with two in each group. In the OS group, one reoperation was necessary because of instrumentation failure and one patient was re-operated because of a wrong level of

instrumentation and decompression during the first operation. In the MASS-group, one patient was re-operated because of deep infection and one for instrumentation failure. Except from the patient treated with revision surgery, no other patient suffered from delayed wound healing or mild infection that led to postponement of radiotherapy or chemotherapy treatment.

The pre-and postoperative hemoglobin was not different between the MASS and the OS group. The survival time was longest in the MASS group 637.9 (range=39-1497 months) vs. 461.4 (range=29-1365 months) in the OS group, but the difference was not significantly different ($p=0.133$). The difference in survival between the MASS and the OS group was further examined via Kaplan-Meier survival curves (Figure 2).

Discussion

In this randomized clinical trial based on 49 patients with MSCC, we found that by using the MASS technique, blood loss was significantly reduced and the operation time was significantly increased compared to open surgery. There was a tendency for a longer survival in the MASS group, when compared to the OS group, but this was not statistically significant.

Table II. Peri- and post-operative characteristics of the patients in the minimal access spine surgery (MASS) and the open surgery (OS) group.

Characteristics	MASS Group, n=23	OS group, n=26	p-Value ²
	Median (range) ¹	Median (range) ¹	
Perioperative blood loss, (l)	0.175 (range=0.030-0.800)	0.500 (range=0.100- 2.000)	0.002
Operation time, (min)	142 (range=72-203)	103 (range=59-435)	0.001
Number of complications	2	2	0.899
Preoperative hemoglobin (mmol/l)±SD	7.9 (range=5.8-10.4)	8.0 (range=5.7-9.5)	0.944
Postoperative hemoglobin (mmol/l)±SD	7.1 (range=5-9.3)	6.7 (range=4.6-8.2)	0.167
Survival in days	637.9 (range=39-1,497)	461.4 (range=29-1,365)	0.133

¹Values are percentages for categorical variables, means (SD) for continuous variables with a normal distribution, or medians (range) for continuous variables with a skewed distribution; ²p-value comparing the MASS and the OS group, assessed using independent *t*-test for continuous variables with a normal distribution and homogeneity of variances, Mann-Whitney test for continuous variables with a skewed distribution and chi-square tests for categorical variables.

Surgical treatment of MSCC patients is primarily a palliative procedure that is offered with the intention of preserving neurologic function and to relieve pain. The decision to offer surgical treatment is complicated by the fact that a large proportion of MSCC patients need oncologic treatment after surgery (11). Common treatments offered are chemotherapy and radiation therapy with the risk of complications like infection and revision surgery. These factors may delay or deprive the MSCC patients of the possibility of adjuvant treatment (12-14). Previous studies have shown that wound complications are seen in 10 percent of all MSCC patients receiving surgical treatment, and that surgery often results in considerable perioperative bleeding (13-15).

One of the major strengths of this study is that it is a one center randomized controlled trial and all patients were operated by a small team of skilled surgeons. There were no dropouts from the study. It can also be considered as a major strength that the treatment facility serves an entire region consisting of 2.5 million people, making the data representative of the country, with a high degree of external validity.

One important limitation of this study was its small sample size. It could be suggested that the inclusion of a larger number of patients into the study would have increased the statistical power to detect a significant difference in the number of reoperations due to wound complications and in survival time between the two groups.

Previous studies have reported a complication rate of 5-10% in patients operated with MASS technique *versus* a complication rate of 7% in the OS groups (13, 14, 16-18). Wound complications that led to revision surgery were registered for all patients. One patient had wound complication, which led to revision surgery. We collected information on prolonged wound healing and postponement of radiotherapy due to prolonged wound healing for all patients. Compared to other previous studies our wound complication rate was low.

Figure 2. Kaplan-Meier survival estimates for patients treated with minimally access spine surgery (MASS) or open Surgery.

Two recent systematic reviews have compared minimal access surgery with open surgery in patients suffering from MSCC (7, 8). Lu *et al.* included six cohort studies (three prospective and three retrospective) representing a total of 252 patients (19-24). Lu *et al.* concluded that there are many surgical advantages to the use of MASS compared with OS, such as reduced blood loss and fewer complications, however, future larger cohort studies and future randomized trials are needed to validate the findings. In the review by Pennington *et al.*, the authors analyzed the same six studies along with two further retrospective cohort studies, thereby including further 21 patients, and concluded that the level of the available evidence is low (25, 26). Both studies emphasize a well-designed study by Hansen-Algenstaedt *et al.* (19). In this study, the authors compared 30 patients treated with OS with 30 patients treated with MASS. Hansen-Algenstaedt *et al.* concluded that MASS can be a

good alternative to conventional OS (19). They found, in accordance with our study, less bleeding in patients treated with MASS. In the Hansen-Algenstaedt study, the operation time was shorter, which is not in line with our findings. The differences may partly be attributable to different MASS procedures at the different hospitals.

In a cohort study by Hikata *et al.*, the authors compared 25 patients operated with MASS with 25 patients operated with OS. The results showed a significantly lower blood loss (340 *versus* 714 ml) and complication rate (3 *versus* 11 patients) in the MASS group (27). We found equal complication rates with 2 complications in each group, which is not in line with the study by T *et al.* The difference in the complication rates in the study by Hikata *et al.* was not discussed but is a very important aspect of the comparison and needs to be addressed and described further in future studies, if a difference is found (27).

In the study by Hansen-Algenstaedt *et al.* the authors concluded that MASS could be the optimal surgical option for patients with the most advanced metastatic disease. MSCC patients are vulnerable and complications from surgery may shorten survival time. The survival time among operated MSCC patients may further be shortened by the delay of adjuvant radiation therapy and chemotherapy. For this reason, we analyzed the difference in survival between the MASS and the OS group. Patients operated with the MASS technique had longer survival times (638 months *versus* 461 months), but this was not a statistically significant difference. More studies, preferably randomized clinical trials, need to be conducted to examine the difference in survival time in a larger MSCC population.

Based on this randomized clinical trial, we conclude that the MASS technique in MSCC patients is associated with less blood loss, but a longer operation time when compared to the OS technique. In our study, the complication rate was equal in the two groups. This knowledge supports what has previously been found in observational studies, however, more or larger RCT's may reveal whether the MASS technique is associated with a longer survival time than the OS technique.

Conflicts of Interest

All Authors declare no conflict of interest in relation to this study.

Authors' Contributions

Søren Schmidt Morgen, MD, Ph.D.: Conceptualization, data curation, formal analysis, writing - original draft, writing - review & editing; Lars Valentin Hansen, MD: Conceptualization, writing - review & editing; Ture Karbo, MD: Data curation, writing - review & editing; Robert Svandal-Stelmer, MD: Data curation, writing - review & editing; Martin Gehrchen, MD, Ph.D.: Conceptualization, writing - review & editing; Benny Dahl, MD, Ph.D., DMSci: Conceptualization, writing - review & editing.

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