ORIGINAL ARTICLE

Comparison of a minimally invasive procedure versus standard microscopic discotomy: a prospective randomised controlled clinical trial

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Abstract A Prospective randomised controlled study was done to determine statistical difference between the standard microsurgical discotomy (MC) and a minimally invasive microscopic procedure for disc prolapse surgery by comparing operation duration and clinical outcome. Additionally, the transferability of the results was determined by a bicentric design. The microscopic assisted percutaneous nucleotomy (MAPN) has been advocated as a minimally invasive tubular technique. Proponents have claimed that minimally invasive procedures reduce postoperative pain and accelerate the recovery. In addition, there exist only a limited number of well-designed comparison studies comparing standard microdiscotomy to a tubular minimally invasive technique that support this claim. Furthermore, there are no well-designed studies looking at the transferability of those results and possible

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Department of Orthopedics, University of Magdeburg, Leipziger Str. 44, 39120 Magdeburg, Germany e-mail: joerg.franke@med.ovgu.de learning curve phenomena. We studied 100 patients, who were planned for disc prolapse surgery at two centres [50 patients at the developing centre (index) and 50 patients at the less experienced (transfer) centre]. The randomisation was done separately for each centre, employing a blockrandomisation procedure with respect to age and preoperative Oswestry score. Operation duration was chosen as a primary outcome parameter as there was a distinguished shortening observed in a preliminary study at the index centre enabling a sound case number estimation. The following data were compared between the two groups and the centres with a 12-month follow-up: surgical times (operation duration and approach duration), the clinical results, leg and back pain by visual analogue scale, the Oswestry disability index, length of hospital stay, return to work time, and complications. The operation duration was statistically identical for MC (57.8 \pm 20.2 min) at the index centre and for MAPN (50.3 \pm 18.3 min) and MC $(54.7 \pm 18.1 \text{ min})$ at the transfer centre. The operation duration was only significantly shorter for the MAPN technique at the index centre with 33.3 min (SD 12.1 min). There was a huge clinical improvement for all patients regardless of centre or method revealed by a repeated measures ANOVA for all follow-up visits Separate post hoc ANOVAs for each centre revealed that there was a significant time-method (MAPN vs. MC) interaction at the index centre (F = 3.75, P = 0.006), whereas this crucial interaction was not present at the transfer centre (F = 0.5, P = 0.7). These results suggest a slightly faster clinical recovery for the MAPN patients only at the index centre. This was due to a greater reduction in VAS score for back pain at discharge, 8-week and 6-month follow up (P < 0.002). The Oswestry-disability scores reached a significant improvement compared to the initial values extending over the complete follow-up at both centres for both methods without revealing any differences for the two methods in either centre. There was no difference regarding complications. The results demonstrate that a shorter operation duration and concomitant quicker recovery is comprehensible at an experienced minimally invasively operating centre. These advantages could not be found at the transfer centre within 25 minimally invasive procedures. In conclusion both procedures show equal mid term clinical results and the same complication rate even if the suggested advantages for the minimally invasive procedure could not be confirmed for the transfer centre within the framework of this study.

Keywords Minimally invasive · Disc surgery · Microdiscectomy · Comparison · Disc herniation · Prospective · Randomised

Introduction

The microscopically assisted percutaneous nucleotomy (MAPN) was developed by Greiner-Perth and Böhm (Bad Berka, henceforth called the index centre) as a tubular system using a muscle splitting posterior approach for lumbar disc surgery [14]. However, a whole number of new methods for the operative treatment of lumbar disc hernia have been developed within the past two decades [7, 9, 11, 15, 32]. The main difference of the MAPN technique to the standard microscopic technique is the transmuscular versus the subperiostal approach.

Nonetheless, there is no valid database on the basis of prospective and randomised studies for the evaluation of these new techniques as outlined in the newest Cochrane review. The review stated that the results of open discectomy and microsurgical discectomy are comparable and that for the acute attack the results are better than of conservative care. Up to now, the evidence on minimal invasive techniques remains unclear [11].

Beside the importance of clinical results, as for example, pain and ADL-scores for the assessment of new methods, the operation duration is one purely objective parameter having an economical importance for the judgement of the usefulness of a new method.

At a preliminary study an operation duration using MAPN of 69 min was reported [13]. After the preliminary study it became obvious that after a corresponding learning curve the operation duration was shorter for the MAPN procedure than using a microsurgical technique. The operation duration gathered from the records of the next 200 cases operated on using MAPN technique at the centre that inaugurated the MAPN procedure revealed a clinically relevant shortening of the operation duration. Therefore, the operation duration was considered as the primary endpoint.

In addition to the primary outcome variable, the clinical results are nonetheless of considerable importance for the assessment of a new technology. The visual analogue scale (VAS) and the Oswestry disability index (OSW) are utilized ensuring that a possible shorter operation duration is not conceived at the expense of poorer clinical outcome.

The sum VAS was chosen as a measure for the individual complete pain, gathered from different pain locations (back and leg pain) together [14].

Our primary hypothesis was that a gain in operation time is comprehensible for the MAPN technique under the conditions of a prospective randomised controlled trial. The clinical results (sum VAS as secondary endpoint and Oswestry disability index) served as control, that there is no speed accuracy trade-off for the MAPN procedure. Additionally, we hypothesized that a shorter operation duration is transferable to another spinal surgery centre with experience in microscopic disc surgery (Magdeburg, henceforth called transfer centre). At the transfer centre, 20 operations using MAPN technique had been performed prior to the study, which was assumed to be sufficient to overcome a usual learning curve.

Materials and methods

The present study is a prospective randomised controlled clinical trial. The two operative techniques standard microscopic technique and MAPN technique were described in detail elsewhere [6, 13, 40].

The study was approved by our local university ethical committee and all the patients consented in writing for their participation.

Operation duration was chosen as primary endpoint e, as it is an objective parameter in order to perform a sound case number estimation using the results of our preliminary studies and results of recently published data comparing minimal invasive procedures to the conventional microsurgical technique [4, 13, 34].

A two-centre design was chosen with the developing (index) centre and a less MAPN experienced (transfer) centre. All procedures in either centre were performed by the same senior surgeon (R.G.-P. or J.F.) or at least assisted by that senior surgeon in order to get more valid results excluding the surgeon factor as far as possible.

The pre-study surgical training of lumbar disc surgeries of both senior surgeons exceeded 300 cases. There was prestudy experience for MAPN technique with 150 cases (R.G.-P.) and with 20 Cases (J.F.).

For case number estimation the mean operation duration was set to 60 min. We adopted a 25% or 15-min reduction

in operation duration using MAPN technique. Under these conditions the two-tailed test with statistical power of 0.8 and an Alpha of 0.05 determined a necessary case number per centre of 48. The case number estimation was done using G-Power [2].

The indication procedure for the disc hernia operations was done according to the guidelines of the main German Orthopaedic and Neurosurgical Association. All included patients showed disc dislocation grades 3–5 according to Krämer et al. [20].

Exclusion criteria were lateral disc hernia, protrusions, absolute emergencies due to cauda equina syndrome, coexisting severe lumbar canal stenosis, Olisthesis, scoliosis greater than 10° , segmental kyphosis greater than 15° , any prior lumbar spine surgeries, underlying malignant or inflammatory disease.

The randomisation was done separately for each centre, employing a block-randomisation procedure with respect to age and preoperative Oswestry score.

The follow-up period was set to 12 months.

The study protocol encompassed operative and clinical data. The operative data consisted of the procedure (MAPN or MC), the duration of the operation as primary endpoint (time between incision and wound closure). Additionally, the time for the approach (time between incision and opening of the spinal canal) and the closure time (time between retraction of the tube or Caspar retractor and the last stitch done) were recorded for each operation. As Amount of removed disc material, intraoperative complications and procedural changes (e.g. changes from MAPN to MC) served as further operative data.

Leg and back pain intensity were measured separately using visual analogue scale (VAS) on a scale 0 (no pain) to 10 (worst possible pain).

The sum VAS as the addition of leg and back pain VAS score was chosen as secondary study parameter. The neurological deficits (paresis grade according to British Medical Research Council, radicular sensory loss) were recorded. The evaluation of their functional capacity was

conducted by using the Oswestry low back pain questionnaire [8, 22, 23].

The postoperative phase patients were provided with a base pain medication of 3×400 mg Ibuprofen.

The length of the hospital stay and the time out of work were recorded as supplementary data.

Follow-up examination took place at 8 weeks, 6 and 12 months.

MAPN operative technique

For the present study, we made minor changes to the technique previously described [13].

Unlike the microsurgical technique the X-ray converter remains in the lateral view within the operation area. The level localisation with a spinal needle was done on the opposite side. The pinpoint was directed at the open interlaminar window. The skin incision of 15 mm at the side of the pathology was performed in height of the needle entry point approximately 2 cm paramedian (Fig. 1a, b).

Both the thoracolumbar fascia and the paraspinal muscles were dilated till the working channel could be brought in. In the context of this study we utilized work channels with an outside diameter of 14 mm. Dependent of the anatomical conditions working channels were available in different lengths (45, 55, 65 mm). This is a change to the earlier described technique with an improved working channel variety compared to the previous. After attaching the grip the pathology oriented alignment of the working channel could be carried out (Fig. 2a). All further work steps were performed under direct vision via microscope in the fundamental technique (Fig. 2b).

Statistics

For analysis of the primary endpoint, the operation duration, a 2×2 ANOVA was done of the factors surgical technique (MAPN, MC) and centre (index centre, transfer centre). The secondary outcome parameter (Sum VAS)

Fig. 1 a Positioning of the dilator. **b** Lateral X-ray with the positioned dilator



Fig. 2 a Positioned working channel with handle. b Microscopic view through the working channel (sequestrated disc in the centre)



analysis was performed utilizing a $2 \times 2 \times 5$ ANOVA of the factors surgical technique and centre and the time of examination (preoperatively, 48 h, 8 weeks, 6 and 12 months, postoperatively). Additionally, we used student's *t* test looking at differences between leg VAS and back VAS score for the two procedures. Provided that there was an interaction between surgical technique and centre, a repeated measure ANOVA was used for each centre separately.

If the Mauchly test of sphericity was significant we used Greenhouse–Geisser correction. In case of a significant difference in the ANOVA an LSD post hoc test was used.

The learning curve assessment was done using the correlation test by Pearson and Spearman between patient number and operation. For all tests the level of significance was assumed with P < 0.05.

Results

Between September 2002 and May 2004, 100 patients were included to the study. A microsurgical procedure underwent 48 and 52 patients a MAPN procedure.

At the index centre 25 patients were randomised to both groups, whereas at the transfer centre 27 patients were randomised to the MAPN group and 23 patients to the MC group.

No significant group differences, neither between the centres nor between the therapy arms as a randomisation control, could be found for preoperative parameters (age, sex distribution, VAS, OSW, paresis and sensory deficits).

The average age of the complete group was 44 years (min 21, Max 72, SD 11.7). There were 40 women and 60 men with an equal distribution between groups.

The pathologic segment was L5/S1 in 42%, L 4/5 in 51%, L3/4 in 6% and L2/3 in 1%.

According to the inclusion criteria we diagnosed 45% free sequestra (degree 5), 42% subligamentous sequestra (degree 4) and 13% subligamentous herniation (degree 3; according to Krämer [20].



The operation duration was analysed by ANOVA which showed a strong centre-method interaction (F = 9.773, P < 0.0001). Post hoc testing revealed, as shown in Fig. 3a, that the duration was statistically identical for MC ($57.8 \pm 20.2 \text{ min}$) at the index centre and for MAPN ($50.3 \pm 18.3 \text{ min}$) and MC ($54.7 \pm 18.1 \text{ min}$) at the transfer centre. The operation duration was only significantly shorter for the MAPN technique at the index centre with 33.3 min. (SD 12.1 min).

For the transfer centre a Spearman rank-correlation analysis between the MAPN operation duration and patient number did not reveal a significant relationship (r = -0.26, P = 0.19), indicating that these results were not due to a learning curve within the study period.

Additionally, for the approach duration, there was a strong centre-method interaction with an *F* value of 18.7 (P < 0.001). As outlined in Fig. 3b the approach duration for MC (11.8 ± 5.4 min) at the index centre and MC (9.7 ± 3.3 min) and MAPN (8.0 ± 4.4 min) at the transfer centre were statistically identical. The time for the MAPN approach at the index centre, however, was significantly shorter.

Regarding the removed amount of disc material the ANOVA revealed no main effects of centre or method and, moreover, no significant centre–method interaction was found. On an average $(1.4 \pm 0.9 \text{ g}; \text{minimum } 0.3 \text{ g}, \text{maximum } 5 \text{ g})$, dry disc material per operation was removed.

Five dural lesions had to be registered to intraoperative complications. These spread out on the MAPN group with two and three on the MC group with no further clinical sequelae. No procedural change, in particular no change from MAPN to MC, was required. Further intraoperative complications did not occur.

Clinical data

There was a huge clinical improvement for all patients regardless of centre or method revealed by a repeated



Fig. 3 a Operation duration at both centres. b Approach duration at both centres

measures ANOVA on the sum VAS for all time points (F = 165, P < 0.0001), Moreover, as shown in Fig. 4a and b, there was a significant centre-method interaction (F = 4.9, P = 0.029). Separate post hoc ANOVAs for each centre revealed that this interaction was due to the fact that there was a significant time-method (MAPN vs. interaction at the index MC) centre (F = 3.75,P = 0.006), whereas this crucial interaction was not present at the transfer centre (F = 0.5, P = 0.7). These results suggest that the clinical outcome of both surgical methods was indistinguishable at the transfer centre, whereas MAPN patients at the index centre showed a slightly faster recovery when compared to MC patients. This was mainly due to the fact the there was a more pronounced reduction in the VAS scale for back pain. This phenomenon reached statistical significance at discharge (P < 0.001), 8 weeks (P = 0.002) and 6-month (P = 0.003) follow up. For the 12-month follow up this difference could not be found (P = 0.467). No difference

was found for the VAS scale for leg pain at any of the time points.

The same analyses for the transfer centre using t tests did not show any difference neither for the leg VAS nor for the back VAS scale at any time point, indicating that there was no statistical significant difference in clinical outcome for these two methods at the transfer centre.

The Oswestry-disability scores reached a significant improvement compared to the initial values extending over the complete follow-up at both centres for both methods (ANOVA with main effect of time, F = 144, P < 0.001). However, the centre–method interaction did not reach the conventional level of statistical significance (F = 3.1, P = 0.08), indicating that the clinical outcome was independent of method at both centres (Fig. 4c, d). There was no significant difference comparing the ODI score at any follow up for both centres.

Preoperatively, 82 patients showed neurological deficits, 33 only sensory disturbances, 49 motor and sensory deficits.

In two cases a deterioration of the neurological situation occurred immediately postoperatively (<48 h), however, it recovered later uneventfully. In 83% of the patients a primarily observed motor deficit resolved completely within the follow up period.

Sensory deficits completely resolved in 68% of the patients, improved in 18%, and remained unchanged in 14%. For the neurological situation there was no obvious difference between centres and methods.

The mean hospital stay at the index centre was significantly shorter for the MAPN group with 3.8 days compared to the MC group with 4.9 days. No difference was found for the transfer centre.

The preoperative working inability was on an average 5.2 weeks (min 1, max 42 weeks). All patients, who were preoperatively in an employment relation, resumed their occupation within 14 weeks, 77% within 8 weeks. The average postoperative inability to work was 7 weeks.

Altogether, seven patients had to have a reoperation (7%). Five patients developed after a symptom free interval (ranging from 3 to 11 months) a genuine relapse (same level, same side). These five patients (four from the MC group, one from the MAPN group) underwent a reoperation using the same technique performed previously. At the remaining two patients (one patient with MAPN and one patient from the MC group) a segmental instability within the follow-up period got apparent due to progressive disc degeneration. Eleven months after the original intervention one total disc arthroplasty was implanted, whereas the other patient underwent a PLIF procedure. No further complications, like cicatrisation disturbances, cerebral fluid zysts or iatrogenic spondylitis did occur.

Fig. 4 a and **c** show the sum VAS and Oswestry time course for the index centre (*filled signs*) and **b** and **d** for the transfer centre (*blank signs*). For the sum VAS scale the timepoints are *1* preoperative, *2* at discharge, *3* 8 weeks p.o., *4* 6 month p.o., *5* 12 month p.o. For the Oswetsry score the timepoints are *1* preoperative, *2* 8 weeks p.o., *3* 6 month p.o., *4* 12 month p.o.. *Circles* indicate MAPN group, *quadrates* indicate MC group



Discussion

The transferability of shorter operation durations of the MAPN procedure as a minimal invasive alternative to the standard microdiscectomy was not found employing the present bicentric study design with 100 patients included. There was a strong centre-method interaction for the operation duration indicating that only at the index centre a temporal advantage for the operation duration could be achieved. The operation duration reported in the literature for a standard microdiscectomy ranging from 54 to 70 min was compatible to our findings for the MC procedures at both centres and even the MAPN procedure at the transfer centre [10, 12, 25, 36, 39]. For an endoscopic procedure using a tubular system Nakagawa reported a duration of 79 min [26]. For the same tubular procedure using direct vision operation durations between 60 [3], 97 [30], 105.7 [25] and 136 min [16] were reported. The average operation duration (MAPN and MC) of 49 min observed in this study was rather at the lower edge of the values known from the literature. After all, the temporal difference performing the MAPN procedures between the index and transfer centre was 27 min. No recognizable learning curve was found in the transfer centre. In turn this meant that a shortening of the operation duration using MAPN technique is not exportable to another centre within the study framework of 25 MAPN patients at the transfer centre. It apparently requires a far higher number of operations in this technique to be able to significantly lower the operation duration. Interestingly the reduction in operation duration showed a positive correlation for 93 patients consecutively operated on using MAPN technique at the transfer centre after the study period (spearman correlation test; rho = 0.526; J. Franke, unpublished observation). Perez-Cruet reported a similar finding as he described for his study an operation duration of 110 min for the first 30 cases and 75 min for the last 30 cases. Thus, the learning curve seems to be somewhere in between 25 and 100 procedures. In a more recent study using a full endoscopic procedure a very short duration for a large cohort has been described. The author report for a far lateral and intralaminar full endoscopic procedure 28 and 29 min [31, 33]. For a randomised controlled trial the same authors report for standard microdiscectomy an OR time of 43 min and for a full endoscopic procedure of 22 min [34]. The large number of cases in the studies indicates a very broad experience with this procedure. These operation durations are fully compatible to the operation duration for the MAPN procedure at the index centre with 34 min and the operation duration registered at the transfer centre after consecutively accomplished additional 93 MAPN procedures.

The approach for the MAPN technique is critical to the visibility and accessibility of the herniated disc within the spinal canal and different to the microsurgical technique. Knowing the centre–method interaction for the complete

operation duration, it is almost to be awaited that the approach duration was shorter at the index centre for the MAPN procedure only. The additional time gap at the transfer centre is probably due to the fact, that the adjustment to working through a tube rather than a more open retractor system takes more than 25 MAPN procedures. As the approach duration was measured till the ligamentum flavum was incised another time factor is routine with the placement of the tubular retractors exactly onto the ligamentum flavum, which is obviously more time consuming for a surgeon less experienced with the MAPN procedure. Any surgeon or even unit that performs only a small number of disc procedures must be aware that a possible time advantage of this new method does not occur within the first 25–35 procedures.

Regarding the clinical results as sum VAS and Oswestry Score Wu et al. [39] found in a study of 821 patients a mean postoperative OSW of 23%, compared to 48% before surgery for a minimal invasive procedure. The VAS dropped on an average from 78 mm preoperatively to 23 mm postoperatively. Östermann reported for the standard discectomy an average drop for the OSW Score for the surgical patients from 39 to 10 at 1 year, and a an average drop for the VAS for the leg pain from 61 to 6 mm and for the back pain from 53 to 19 mm at 1 year postoperatively [28]. Thus, our clinical results measured by means of the OSW Score and the sum VAS with additional respect to the clinical data meet the criteria for a successful disc removal procedure as compared to the results from the abovementioned literature [11].

The sum VAS did show a time-method interaction only at the index centre. Therefore, it has to be concluded that the faster pain relief is mainly due to the shorter operation duration in conjunction with the minimally invasive procedure as we found no such differences at the transfer centre. If there had been a clinical relevant effect of the smaller muscle trauma only due the MAPN technique this should have been also found at the transfer centre.

The results of the Oswestry score did not show any differences either for the time course or for the centre comparing the two methods. In summary of those clinical results obviously only the shorter operation duration in conjunction with a less traumatizing technique at the index centre did show an effect for the patients comprising of a slightly faster pain relief and recovery. The hypothesis that a minimised approach trauma alone leads to a lesser tendency of pain chronification could not be confirmed. Furthermore, our conclusion is that the proposed faster recovery after a minimal invasive disc procedure is not only depending on the method itself but the experience of the performing surgeon with the method. It seems to be true that after a certain time period a smaller skin incision does not inevitably lead to less pain. This is confirmed by a recent study comparing discectomy with or without a retraction system [19].

Our clinical results confirmed the equal efficacy of both methods of decompressing the spinal canal, which is of paramount importance for the introduction of a less invasive technique. The postoperative length of the hospital stay is a considerable economic factor like the operation duration, particularly under the DRG in Germany. Jansson et al. [17] found in a swedish analysis in a patient collective after lumbar disc operations covering 27,576 patients with a mean hospital stay of 5 days. Muramatsu reported 8.1-23.8 days and Schwetlick a shorter stay of 4 days [25, 35]. Our results with an average hospital stay of 5 days are within those limits. Regarding this there also was a centre-method interaction. A shorter hospital stay was only present for the index centre MAPN group. Admittedly, the length of hospital stay is a rather "soft" parameter within the German system, which is influenced by many subjective things, but it corresponded well with the findings of the sum VAS Score as secondary outcome parameter. Regarding the re-operation rate, Östermann reported 14% after lumbar intervertebral disc operations in a population of 35,309 patients in a period of 11 years [29]. In large cohort- and population-based studies with follow-up periods ranging from 4 to 10 years revision rates between 5 and 19% were observed [5, 18, 21]. For studies with a shorter follow-up period of 3-year revision rates between 4 and 11% are documented [12, 24, 33, 38]. Our revision rate of 7% for a 1-year follow up lies within the ranges known from the literature.

Intraoperative complications consisted of only dural lesions. We had to register 5% which is marginally higher than the figures reported in the literature's greatest patient cohort by Oppel et al. [27, 37] of 3.7% and for the SPORT study. As looking at a minimal invasive procedure with a potentially higher risk of dural lesions we did not find any differences between the procedures. Nerve root lesions did not occur as well as further complications, like wound infections or Spondylodiszitis. Thus, it can be stated that MAPN and MC are procedures with almost identical operative safety.

Regarding the duration of the inability to work Andrews and Williams estimated a time of 5.2 weeks [1, 38], whereas Muramatsu et al. [25] reported 2–3 months. For the present study collective the inability to work duration was at most 14 weeks. Seventy-seven percent of the patients being in occupation were back to work within 8 weeks. This confirms the known fact that the inability to work duration in Germany and also in Japan are essentially longer than for example in the United States, but the results of our study are within normal limits for a disc hernia procedure for both methods. In summary, the present study showed that the transferability of shorter operation duration and concomitant clinical advantages of a minimally invasive procedure is not given within 25 minimal invasive procedures. We can conclude that for both procedures the safety for disc removal procedure concerning the clinical results and possible complications is given.

Within the study period no real clinical advantage of the less traumatized posterior muscles could be found.

Thus, the hypothesis that a less traumatized back muscle leads not only to a quicker recovery but also to less chronic back pain could not be confirmed.

Clearly the results of this prospective randomised transferability study and the achievement of the same reduction in OR time after the learning curve at the transfer centre strongly suggest a follow-up study at the transfer centre to verify the results at the index centre and a longterm follow-up study with larger samples looking at clinical relevant differences between both techniques as there is still controversy if there are long-term differences between muscle splitting and subperiostal approaches.

Ethical approval

The present study was approved by the local ethical committee of the University of Magdeburg.

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