

Faculty of Health Sciences

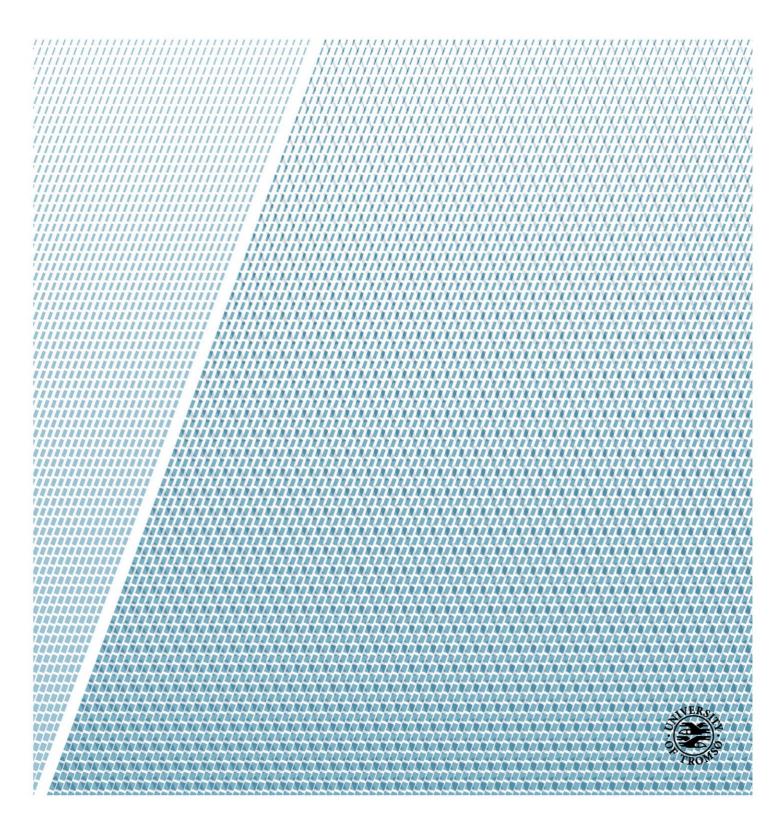
Endoscopic treatment of the Retro-trochanteric Pain Syndrome

A quality study with medium-term follow-up

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Preface

The orthopaedic research group at UiT The Artic University of Norway with MD. PhD Khaled Meknas in front have had a special interest in Retro-trochanteric pain syndrome and treatment of this condition for several years. In the past ten years or so Meknas has operated patients with Retro-trochanteric pain syndrome at the University Hospital of Northern Norway with endoscopic bursectomy and microtenotomy of short rotator in the hip. The purpose of this project is to evaluate this new treatment method and if there is developed osteoarthritis or other pathology in the hip region in the operated patients.

Meknas has been my supervisor and has designed this study and its objective. He has also provided the preoperative and the short-term data. Furthermore, he dedicated two days in his outpatient clinic together with the writer for the medium-term follow-up. MD Zeiad Al-Ani (radiologist) has interpreted the x-ray and MRI scans. Professor Tom Wilsgaard has offered his assistance with the statistical methods. Sincere thanks to MD Meknas for offering me this project and for excellent supervision. Thanks to all that have contributed to the project.

Tromsø, 31.05.2018

Eink Millelsen

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Abstract

Introduction

Retro-trochanteric pain syndrome (RTPS) is a condition characterized by pain and tenderness in the buttock region. Normally sciatica originates from pathology in the spine. In RTPS the pathology resulting in sciatica is localized in the buttock region. First line treatment for RTPS is physiotherapy. This study evaluate treatment of RTPS by endoscopic bursectomy and microtenotomy of the short rotator affecting the sciatic nerve.

Patients and methods

11 patients (12 hips) operated with endoscopic bursectomy and microtenotomy of a short rotator for treatment of RTPS were included in the study. The average age of the patients (1 male and 10 female) were 57.2 years and the mean duration of symptoms were 6.7 years. All patients had failed preoperative attempts of conservative treatment such as physiotherapy, NSAIDs and local steroid injections. The short-term follow-up was 3 months and the mean medium-term follow-up was 5 years. We evaluated the level of pain (using the visual analogue scale, VAS), function and clinical examination preoperatively, at 3 months and at 5 years. We also evaluated level of satisfaction and postoperative time without symptoms. Standard radiographs of the pelvis and hips and MRI of the lumbar spine, pelvis and hips were done preoperative and at medium-term follow-up.

Results

Pain significantly decreased from a mean VAS of 8.3 (SD 0.99) to 2.4 (SD 1.7), p-value = 0.002 at short-term and 5.1 (SD 2.6), p-value = 0.006 at medium-term follow-up. The ability to sit and usage of pain medication had a significant improvement. Overall satisfaction was high. Between surgery and final follow-up five patients developed OA in the hip(s).

Conclusion

Endoscopic bursectomy and microtenotomy of the small rotators in the hip are a valuable treatment method for patients with RTPS, the patients had significantly reduced pain and improved function five years after operation.

Introduction

Retro-trochanteric pain syndrome (RTPS) is a condition characterized by pain and tenderness in the buttock region from the sacrum to the greater trochanter, often accompanied by sciatic pain radiating diffusely to the lower extremity, limping and intolerance of sitting more than 20-30 min (1, 2). The syndrome is known through different terms such as 'piriformis syndrome', 'greater trochanteric pain syndrome' (GTPS), 'internal obturator syndrome' and 'deep gluteal syndrome' among others (1, 2). We choose to use the term Retro-trochanteric pain syndrome because it is a broader term and it is recommended by Meknas et al. (1).

The incidence of the syndrome is not very well mapped out, as it is an exclusion diagnosis. However, the lifetime prevalence is estimated between 10-25% in industrialized societies (3-5). The incidence in primary care setting is reported to be around 1.8 patients per 1000 per year (4). The spine surgeon Tortolani and colleges found GTPS in 62.7 % of patients they evaluated(6). The incidence is increased in women, patients with leg length discrepancies, low back pain and knee pain (1).

Usually sciatic pain originates from pathology in the spine such as radiculopathy or lumbar spinal stenosis, which is not the case for RTPS. The aetiology of the syndrome is not clearly known, but many factors are reported in the literature. Anatomical variations or abnormalities in the piriformis muscle and the sciatic nerve (7) such as piriformis muscle anterior to the sciatic nerve (8), bipartite piriformis muscle (9, 10) or a split sciatic nerve that encircles the piriformis muscle may irritate the nerve and give pain (1). Carro et al. found adhesions between the sciatic nerve and the piriformis muscle and fibrous or fibrovascular bands limiting the movement of or compressing the sciatic nerve (2). The gemelli and internal obturator muscles complex and their associated bursae may cause pain (11). It is argued that trochanteric bursitis is a frequent cause of 'hip' pain (12). Overuse, hypertrophy of the piriformis muscle or dynamic entrapment of the sciatic nerve by the piriformis may cause the piriformis syndrome, (2, 13). In two different studies; Park et al. and Yang et al. found ganglion cysts compressing the sciatic nerve causing sciatic pain (14, 15). Ischiofemoral pathology, pathology in the quadratus femoris and the hamstrings may affect the sciatic nerve and cause pain (2). Pyomyositis of the piriformis or the internal obturator is reported to cause RTPS (16, 17). It is also reported RTPS secondary to hip replacement (18).

Cox et al. (11) reported that inflammation of the small external rotators and thus tendinosis of these muscle tendons may cause RTPS. Radiofrequency microtenotomy has been reported effective for treatment of lateral epicondylitis (19-21), patellar- and rotator cuff

tendinosis (22). Therefore Meknas et al.(1) suggested microtenotomy of the affected external rotator as a possible method for treatment of RTPS.

The Diagnosis

The syndrome is characterized by buttock and diffuse pain in the lower extremity caused by a hypertrophic or inflamed muscle, which increases the pressure from the small external rotators of the hip towards the sciatic nerve (11). Another specific symptom is disturbed or loss of sensation in the affected extremity, usually diffuse and not limited to a dermatome (1, 2).

The main diagnostic sign seems to be pain or tenderness triggered by deep digital palpation over the external rotators of the hip and the sciatic nerve (23, 24). Other useful clinical tests include Freiberg's sign, Pace's sign, Lasegue's test, Trendelenburg's sign and muscle hypotrophy in the affected extremity (1, 2). Most patients with RTPS have an immediate positive response to injection of a local anaesthetic and corticosteroid in the area, which can be used both for diagnosis and therapy of the condition (25).

Regarding laboratory and radiological diagnostic there is no method available to diagnose the syndrome (1, 26-29). However, standard radiographs of the pelvis and hips, and MRI of the lumbar spine and hips are useful to exclude differential diagnosis such as radiculopathy, lumbar spine stenosis, osteoarthritis (OA), femoro-acetubular impingement and gynaecological conditions that should be excluded before making the diagnosis (1, 2).

Treatment

A number of methods exist for the treatment of RTPS. Physical therapy is recommended as first line treatment (11, 24, 30). Other conservative methods such as non-steroidal antiinflammatory drugs (NSAIDs), muscle relaxants, ice and rest have been reported with good outcome (31, 32). Injections of anaesthetic agents with or without corticosteroids are reported with variable results (33, 34). Tendinopathies in other muscles are treated with extracorporeal shock wave therapy (ESWT) and injection of platelet-rich plasma (PRP), this may be an alternative treatment for RTPS (35-38).

Several studies have been reported an immediate pain relief after tenotomy of the piriformis tendon (8, 9, 39, 40). Carro et al. (2) described an endoscopic surgical technique for piriformis tendon and fibrotic band release for patients with RTPS , they found the method useful and that it improved function and diminished pain. Meknas et al. (23, 41) described

long-term improvement after tenotomy of the internal obturator muscle in patients with a tense internal obturator tendon. Meknas et al .(1) suggested a treatment algorithm for RTPS.

A procedure for treating RTPS that included endoscopic trochanteric bursectomy and microtenotomy of the short rotator affecting the sciatic nerve is described by Meknas et al. (1) The unpublished short-term data showed pain reduction and improved function. Some of these patients are also included in the current study.

Objective

New methods of treatment need to be evaluated. This project aims to evaluate the treatment of patients with retro-trochanteric pain syndrome operated with endoscopic bursectomy and microtenotomy of short rotators in the retro-trochanteric area. Our hypothesis is that the patients suffered from retro-trochanteric pain syndrome would have reduced pain and improved function at medium-term follow-up after endoscopic bursectomy and microtenotomy of the short rotators of the hip. Additionally, we aimed to evaluate if OA or other pathology in the hip region would develop during the follow-up period.

Ethics and Protection of Privacy

The Data Protection Official at the University Hospital of Northern Norway were contacted through Kristin Andersen. The Data Protection Official have evaluated the project to be regulated by § 7-12 in the Personal Data Regulations and authorized by the Health Personal Act § 26. According to the Data Protection Regulations § 7-12 did the Data Protection Official authorize project. See enclosure 1 for the full sanction.

Patients and methods

Patients

Eleven patients (twelve hips) one male and 10 female, mean age 57.2 (SD 10.6) years who had retro-trochanteric pain syndrome, with radiation to the lower extremity treated by endoscopic bursectomy and microtenotomy of the short rotators, were included in the study. The mean duration of symptoms was 6.7 years (SD 3.9). The demographics of the patients are presented in table I. The surgical procedure was described by Meknas et al. in 2011 (1). All patients had been through previous attempts of conservative treatment such as physical

therapy, NSAIDS and injections of local anaesthesia with corticosteroids without improvement. Patients with cancer or serious organ system failure, or poor general condition were excluded.

Methods

Preoperatively, at 3-month follow-up and at 5-year follow-up, all patients underwent both assessment of pain using the visual analogue scale (VAS), assessment of function and clinical examinations. Furthermore, registration of time without symptoms postoperatively, satisfaction, willingness to undergo a reoperation given the same symptoms as preoperatively and scoring by The Nonarthritic Hip Score (42) were done at the medium-term follow-up.

The evaluation of function included assessment of ability to sit and walk and usage of analgesics and NSAIDs. Classification of function is presented in table II. The clinical examinations included Pace's sign, Freiberg's sign, Lasegue's test, Trendelenburg's sign, test for pain when examined with deep digital palpation over the small external rotators and the sciatic nerve, radiation of pain and evaluation of limping.

Preoperatively and at final follow-up, all patients underwent standard antero-posterior radiographs of the pelvis and hips, and lateral view of the hips (bilaterally) and MRI of the lumbar spine, pelvis and hips using a Philips Intera 1.5 Tesla (Royal Philips, Electronics Amsterdam Netherlands). An independent radiologist described both the preoperative and medium-term follow-up x-rays and MRI scans. Calcaria in the area of the Greater Trochanter were graded as +/++ or -. OA in the hips were graded from 0-IV according Conventional radiograph grading of OA as following:

- grade 0: normal
- grade I: possible joint space narrowing and subtle osteophytes
- grade II: definite joint space narrowing, defined osteophytes and some sclerosis, especially in the acetabular region
- grade III: marked joint space narrowing, small osteophytes, some sclerosis and cyst formation and deformity of femoral head and acetabulum
- grade IV: gross loss of joint space with above features plus large osteophytes and increased deformity of the femoral head and acetabulum

Primary endpoints were registration of pain using VAS, function and satisfaction. Secondary endpoint was medium-term radiological examination and comparison with preoperative radiological examinations. An overview of the variables used is presented in table III.

Statistics

The related samples Wilcoxon signed rank test was used for the longitudinal comparisons. Dichotomous variables were analysed using the McNemar test. For the Pace's sign and Pain radiation the p-value is calculated with preoperative scoring of positive tests 11/12, thus the calculated p-value for these variables is higher than the true p-value. The statistical test was done by using SPSS® Statistics version 24 (International Business Machines, New York, United States). A *p*-value < 0.05 was considered statically significant.

Clarification of terms

RTPS: Retro-trochanteric pain syndrome.

GTPS: Greater trochanteric pain syndrome.

Freiberg's sign: Forced passive internal rotation of the extended lower limb produces pain.

Pace's sign: Resisted external rotation and abduction of the thigh in sitting position produces pain.

Lasegue's test: Buttock and radiating pain below the knee during passive straight leg raise ($<60^\circ$) of the extended lower limb in the supine position.

Trendelenburg's sign: With the patient standing on one foot the pelvis drops on the contralateral side if the abductor musculature is weak.

MRI: Magnetic resonance imaging.

NSAIDs: Non-steroidal anti-inflammatory drugs.

Tendinopathy: A term that is commonly used in chronic tendon disorders when the patient seeks help as a result of pain.

Tendinosis: A histological confirmation of degenerative changes without

inflammatory cells but with changes such as collagen fibril disorientation, rounding of tenocyte nuclei, increased ground substance and hypervascularity in the histological specimens.

ESWT: Extracorporeal shock wave therapy.

Microtenotomy: The Topaz electrode (Smith Nephew) with 1.0 mm tip diameter is used to perform radiofrequency (RF) applications on the tendon in a grid-like

pattern. The electrode connected to sterile isotonic saline flow system, is used for microtenotomy. A radiofrequency apparatus provided the energy delivered through the electrode. The bipolar radiofrequency -based microtenotomy is thought to induce healing by a controlled inflammatory response followed by a stimulation of an angiogenic healing in the tendon.

VAS: Visual analogue scale.

OA: Osteoarthritis.

Calcaria: Calcareous deposition around the greater trochanter and its tendon insertions.

FCF: Fracture of the collum femoris

Results

There was a significant decrease in pain both at 3 months and at 5 years compared to preoperative pain. Mean VAS decreased from 8.3 (SD 0.99) to 2.4 (SD 1.7) p=0.002 and 5.1 (SD 2.6) p = 0.006 respectively (Table IV).

The ability to walk, sit and usage of painkiller are presented in table V. Both the sitting ability and the usage of painkillers had a significant improvement at both follow-ups compared to the preoperative level. The walking ability improved significantly at the short-term follow-up compared to before surgery, however at medium-term follow-up the improvement of walking ability was not significant.

Nine of the patients was symptom free for several years postoperatively (mean 3.4 years, SD 2,5), most of the patients were satisfied with the surgery, and nine were willing to do a reoperation (if they hypothetically were to have the same symptoms as before the operation) (Table VI).

All clinical examination tests preoperatively, at 3 months and 5 years are presented in Table VII.

The radiological findings are presented in table VIII. Preoperatively, none of the patients had pathological changes in the lumbar spine needing surgical intervention. Two patients had unaltered herniation of intervertebral disc at 5-year follow-up.

Calcaria (+) in the area of the Greater Trochanter was found in eight hips before surgery. The corresponding was found in nine hips (one on the contralateral side) at 5-year follow-up, one had developed to ++.

None of the patients had OA in the hips preoperatively. The corresponding was found in 5 patients at medium-term follow-up, two of these patients had developed bilateral OA. Of the five patients with OA, one had tendinopathy revealed by MRI examinations both preoperatively and at 5-year follow-up. The others had developed tendinopathy between the operation and the final follow-up.

The MRI displayed one tendinopathy and three bursitis (of which one was at the contralateral side) preoperatively. At the final follow-up; the MRI displayed tendinopathy in the gluteus medius and / or in the small rotators in eight patients (of which two was on the contralateral side). Furthermore, the MRI casually revealed ovarian cancer in one of the patients. The cancer was successfully treated by the Gynaecologists and Oncologists at the University Hospital of Northern Norway.

One patient had transient neuralgic pain anteriorly to the knee radiating to the lateral leg postoperatively which recovered after 3 months. The pain is most likely derived from irritation of the sciatic nerve during the surgery. No other complications were registered.

Discussion

The most important finding in this study is that pain significantly decreased. At the 3-month follow-up all the patients had less pain compared to preoperative, and at 5 years the corresponding was 9 patients. In addition, both the ability to sit, and the usage of painkillers were significantly improved at both follow-ups. These findings together show that our patients had less pain and better function after the operation.

The tendency of our results is that the patients were satisfied and had good outcome of the operation both on pain and function. There was still a degree of relapse of symptoms between the short- and medium-term follow-up. The negative development seems to be driven by patient no. 1 and 5. Both patients had comorbidity that were interpreted to contribute to their bad scorings. One patients got serious relapse 6.5 years after operation and were re-operated with excellent short-term results.

All things considered the operation was effective both on short- and medium-term and the overall degree of satisfaction was high.

In a recently published systematic review of surgical management of deep gluteal syndrome Kay et al.(43) found varying surgical procedures for deep gluteal syndrome. The review concluded that the results showed consistent improvement in pain and a low incidence of complications after surgery, this is in line with in this study. Among the articles included in the review there were only one randomized controlled trial (RCT). In the RCT by Meknas et al. (23), they found significant improvement of pain both short- and long-term after surgical release of the internal obturator tendon. A median VAS of 8.3 at inclusion decreased to 4.0 at the 8-year follow-up. In a retrospective study in 2017 Han et al. (44) found significant improvement of pain in 12 patients after resection of the piriformis tendon, trochanteric bursectomy and sciatic nerve neurolysis. The mean VAS score of 9.0 decreased to 3.1 at 12-month follow-up. Martin et al. (45) found decrease in pain using VAS from 6.9 to 2.4 and improved modified Harris Hip-Score (MHHS) in 35 patients operated with endoscopic decompression of the sciatic nerve. Furia et al. (35) found that ESWT can be used to treat patients with GTPS that have failed other conservative treatment approaches. They found a significant decrease of pain from 8.5 to 2.7 at 12 months.

Taken together; the findings in this study are in line with other studies in the literature. However, we find few articles with a long-term follow-up. There is, to our knowledge, in the literature not described a procedure involving bursectomy and microtenotomy of the affected short external rotator for treatment of RTPS

In a histological and ultrastructural study, Meknas et al. (46) studied the internal obturator tendon in patients diagnosed with OA or fracture of the collum femoris (FCF) who underwent hip arthroplasty. They found significant altered pathological and ultrastructural appearance (compatible with tendinosis) in the internal obturator tendons in the patients with OA compared to the patients with FCF. To our knowledge, there are no reports in the literature that discuss whether the tendinous changes are a normal pathological process in conjunction with OA, or whether the disease actually starts in the tendon and then proceeds to the joint. Our study does not give an answer on this matter but show the same tendency that tendinopathy and OA are associated with one another.

The strength of this study is medium-term follow up (mean 5 years), and that examiners independent of the surgery performed the medium-term follow-up and all radiographic assessments.

The weakness of the study is the small number of patients involved, the lack of a control group, that the study design was not an RCT and that the time between surgery and the medium-term follow-up was not constant between the patients.

It is desirable that further randomized controlled studies with a greater number of patients are conducted to evaluate both this treatment method and to establish a golden standard for treatment of retro-trochanteric pain syndrome.

Conclusion

Endoscopic bursectomy and microtenotomy of the affected short rotator in the hip resulted in significant medium-term decrease in pain and improved function in patients with retrotrochanteric pain syndrome. Thus, the hypothesis of the present study could be verified. This lends credence to that the surgical procedure can be offered to patients suffering from RTPS resistant towards conservative treatment.

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Tables

Table I Demography of the patients

| ID | GENDER | SIDE | AGE | DURATION OF SYMPTOMS (YEARS) | TIME BETWEEN SURGERY AND MEDIUM-TERM FOLLOW-UP (MONTHS) |
|-------|----------------------|-------------------|--------------------------------------|------------------------------------|---|
| 1 | Female | Right | 72 | 15 | 93 |
| 2 | Female | Left | 51 | 7 | 78 |
| 3 | Female | Left | 67 | 8 | 95 |
| 4 | Female | Left | 71 | 10 | 95 |
| 5 | Male | Right | 65 | 3 | 85 |
| 6 | Female | Right | 42 | 4 | 69 |
| 7 | Female | Right | 61 | 5 | 61 |
| 8 | Female | Right | 55 | 10 | 48 |
| 9 | Female | Left | 44 | 3 | 33 |
| 10 | Female | Left | 50 | 2 | 28 |
| 11 | Female | Right | 51 | 7 | 32 |
| | | Left | | | 30 |
| TOTAL | 10 Females 1 Male | 6 Right 6 Left | Mean: 57.2 (SD ¹ 10.6) | Mean: 6.7 (SD ¹ 3.9) | Mean: 62.3 (SD ¹ 27.1) |

¹SD= standard deviation

Table II Classification of function

| Classification of walking ability | |
|---|---|
| Can walk without problem | 1 |
| Can walk 1 km without pain | 2 |
| Can walk 1/2 km without pain | 3 |
| Can walk only with crutches | 4 |
| Cannot walk | 5 |
| | |
| Classification of sitting ability | |
| Can sit without problem | 1 |
| Can sit 1 h without pain | 2 |
| Can sit 1/2 h without pain | 3 |
| Can only sit 10 min because of pain | 4 |
| Cannot sit at all | 5 |
| | |
| Classification of pain medication | |
| Can manage the pain without painkillers | 1 |
| Painkillers gives moderate effect on the pain | 2 |
| Painkillers have no effect on the pain | 3 |

Table III Variables

| able III Variables | |
|---|--|
| Gender | Defines whether the patient is male or female |
| Side | Defines which hip that was operated |
| Age | Defines the patients age at the time of surgery |
| Duration of symptoms | Defines how long the symptoms lasted before surgery (in |
| | years) |
| Time between surgery and medium-term | Defines how long time between surgery and medium-term |
| follow-up | follow-up (in months) |
| Time without symptoms postoperatively | Defines how long time the patient was free of symptoms |
| | postoperative (in years) |
| Satisfaction with the operation | Defines how satisficed the patient was with the operation on |
| | a scale from 0-10 (0 not satisfied and 10 totally satisfied) |
| Given the same symptoms as | Defines whether or not the patient would have had a new |
| preoperatively would you have wanted a | operation given he/she had experienced the same symptoms |
| new operation? | as preoperative |
| Nonarthritic Hip Score (0-100) at medium- | Defines the score at The Nonarthritic Hip Score on a scale |
| term follow-up | from 0-100 (0 is the lowest possible score and 100 maximum |
| | score) |
| Pain using VAS | Defines the patients pain from the hip using the Visual |
| | Analogue Scale from 0-10 (0 is no pain and 10 is maximum |
| | imaginal pain) |
| Walking ability | Defines walking ability using a scale from 1-5, see table II |
| Sitting ability | Defines sitting ability using a scale from 1-5, see table II |
| Pain medication | Defines pain medication using a scale form 1-3, see table II |
| Lasegue's test | Defines whether or not Lasegue's test is positive under 60 |
| | degrees flection |
| Freiberg's sign | Defines whether or not Freiberg's sign is positive |
| Pace's sign | Defines whether or not Pace's sign is positive |
| Trendelenburg's sign | Defines whether or not Trendelenburg's sign is positive |
| Limping | Defines whether or not the patients are limping |
| Pain radiation in the affected extremity | Defines whether or not the patient experiences pain radiating |
| | down the affected lower extremity or towards the lumbar |
| | column. |
| Radiological findings | <u>Calcaria on x-ray:</u> |
| | Calcareous deposition around the Greater Trochanter major. |
| | Graded as + or ++ |
| | <u>Osteoarthritis on x-ray:</u> |
| | Osteoarthritis in the hips graded from 0-VI |
| | Tendinopathy on MRI: |
| | Whether or not there is tendinopathy revealed by MRI |
| | |
| | |
| | Bursitis on MRI: Whether or not there is bursitis revealed by MRI |

| ID | PREOPERATIVE | SHORT-TERM FOLLOW-UP | MEDIUM-TERM FOLLOW- UP |
|---|----------------|----------------------|---------------------------|
| 1 | 8 | 4 | 9 |
| 2 | 9 | 3 | 6 |
| 3 | 10 | 0 | 2 |
| 4 | 10 | 0 | 3 |
| 5 | 8 | 5 | 10 |
| 6 | 7 | 2 | 5 |
| 7 | 8 | 3 | 5 |
| 8 | 8 | 3 | 6 |
| 9 | 7 | 0 | 1 |
| 10 | 8 | 4 | 4 |
| 11 | 9 (right side) | 2 (right side) | 5 (right side) |
| | 8 (left side) | 3 (left side) | 5 (left side) |
| MEAN (SD ¹) | 8.3 (0.99) | 2.4 (1.7) | 5.1 (2.6) |
| MEDIAN (RANGE) P-VALUES ² | 8 (7-10) | 3 (0-5) 0.002 | 5 (1-10) 0.006 |

Table IV VAS preoperatively, at 3-month and 5-year follow-up

¹SD= Standard deviation

² P-values versus preoperative

Table V Function

| | PREOPERATIVELY | SHORT-TERM FOLLOW-UP | MEDIUM-TERM FOLLOW-UP |
|---|----------------|-------------------------|----------------------------|
| MEAN WALKING ABILITY (SD ¹) | 3,1 (0,30) | 1,3 (0,47) | 2,1 (1,3) |
| MEDIAN WALKING ABILITY (RANGE) | 3 (3-4) | 1 (1-2) | 2 (1-5) |
| P-VALUES ² | | 0,002 | 0,056 (n.s. ³) |
| MEAN SITTING ABILITY (SD ¹) | 3,3 (0,47) | 1,5 (0,69) | 2,2 (0,98) |
| MEDIAN SITTING ABILITY (RANGE) | 3 (3-4) | 1 (1-3) | 2 (1-4) |
| P-VALUES ² | | 0,002 | 0,006 |
| MEAN PAIN MEDICATION (SD ¹) | 2,6 (0,52) | 1,5 (0,69) | 1,6 (0,67) |
| MEDIAN PAIN MEDICATION (RANGE) | 3 (2-3) | 1 (1-3) | 2 (1-3) |
| P-VALUES ² | | 0,003 | 0,008 |
| ¹ SD= Standard deviation | 1 | | |

² P-values versus preoperative
 ³ n.s.= Not significant

| ID | NONARTHRITIC HIP SCORE (0-100) AT MEDIUM-TERM FOLLOW- UP | TIME WITHOUT SYMPTOMS POSTOPERATIVELY (YEARS) | SATISFACTION WITH THE OPERATION (0-10) |
|--|---|--|---|
| 1 | 24 | 2 | 7 |
| 2 | 58 | 4 | 10 |
| 3 | 71 | 8 | 10 |
| 4 | 68 | 7 | 10 |
| 5 | 58 | 0 | 0 |
| 6 | 59 | 5 | 10 |
| 7 | 66 | 2 | 10 |
| 8 | 55 | 3 | 10 |
| 9 | 98 | 3 | 10 |
| 10 | 71 | 0 | 5 |
| 11 | 58 | 3 | 8 |
| MEAN (SD¹) ¹ SD= Standard de | 62.4 (17.5) eviation | 3.4 (2.5) | 8.2 (3.2) |

Table VI Nonarthritic hip score, postoperative time without pain and satisfaction

Table VII Clinical assessment

| | PREOPERATIVE | SHORT-TERM FOLLOW-UP | MEDIUM-TERM FOLLOW-UP |
|------------------------------|--------------|-------------------------|-----------------------------|
| LASEGUE'S TEST POSITIVE | 11/12 | 2/12 | 1/12 |
| P-VALUES ¹ | | 0.004 | 0.002 |
| FREIBERG'S SIGN POSITIVE | 10/12 | 1/12 | 3/12 |
| P-VALUES ¹ | | 0.004 | 0.016 |
| PACE'S SIGN POSITIVE | 12/12 | 4/12 | 5/12 |
| P-VALUES ¹ | | 0.016* | 0.031* |
| TRENDELENBURG'S SIGN | 11/12 | 3/12 | 2/12 |
| P-VALUES ¹ | | 0.008 | 0.004 |
| LIMPING | 9/11 | 1/11 | 3/11 |
| P-VALUES ¹ | | 0.008 | 0.031 |
| PAIN RADIATION | 12/12 | 2/12 | 6/12 |
| P-VALUES ¹ | | 0.004* | 0.063* (n.s. ²) |
| D values versus preeperative | | | |

¹ P-values versus preoperative ² n.s.= Not significant

* P-value calculated with preoperative scoring set as 11/12, thus the calculated p-value is higher than the true pvalue

| Table VII | I Radiogra | phic findings |
|------------------|------------|---------------|
|------------------|------------|---------------|

| ID | STANDARD R | ADIOGRAPHS | MRI | | |
|-----|----------------------------------|--|------------------------|--|--|
| | PREOPERATIVE | MEDIUM-TERM FOLLOW-UP | PREOPERATIVE | MEDIUM-TERM FOLLOW-UP | |
| 1 | Calcaria (+) | Calcaria (+) + Bilateral OA ¹ , grade II at the ipsilateral side and grade III at the contralateral side | Tendinopathy | Tendinopathy | |
| 2 | Calcaria (+) | Calcaria (+) | No pathology | No pathology | |
| 3 | Calcaria (+) | Calcaria (+) + -OA ¹ grade I | Bursitis | Tendinopathy + Bursitis | |
| 4 | Calcaria (+) | Calcaria (+) + OA ¹ grade I | No pathology | Tendinopathy + Bursitis | |
| 5 | Calcaria (+) | Calcaria (++) + Bilateral OA ¹ grade II | Bursitis | Bilateral tendinopathy + Bilateral bursitis | |
| 6 | No pathology | No pathology | No pathology | Contralateral tendinopathy + Contralateral bursitis | |
| 7 | Calcaria (+) | Bilateral calcaria (+) | No pathology | Bursitis | |
| 8 | No pathology | No pathology | Contralateral bursitis | No pathology | |
| 9 | Calcaria (+) | Calcaria (+) | No pathology | Tendinopathy + Bursitis | |
| 10 | No pathology | No pathology | No pathology | No pathology | |
| 11* | Calcaria (+) at the left side | Calcaria (+) at the left side + OA ¹ grade II at the left | No pathology | Tendinopathy at the right side Bursitis at the left side | |
| | | side | | | |

¹OA= Osteoarthritis *the patient is operated in both hips

Enclosure

Enclosure 1



Til Khaled Meknas Ortopedisk avdeling

Deres ref .:

Vår ref.: 2017/3168 Saksbehandler/dir.tlf.: Kristin Andersen/77626506 Dato: 9.6.2017

PERSONVERNOMBUD

GODKJENNING AV BEHANDLING AV PERSONOPPLYSNINGER

Det vises til Meldeskjema for forskningsprosjekt, kvalitetsprosjekt og annen aktivitet som medfører behandling av personopplysninger som er melde- eller konsesjonspliktig i henhold til helseregisterloven og personopplysningsloven med forskrifter, mottatt 18.5.2017. Meldingen gjelder prosjektet/registeret:

Nr. 0707 *Navn på prosjektet: Retrotrochantær hofte smerte*

Prosjektet er et *kvalitetsprosjekt/Studentoppgave* hvor Universitetssykehuset Nord-Norge HF er behandlingsansvarlig.

Formål: «Evaluering av resultat av behandling av isjias lignende smerte rundt hoften»

Personvernombudet (PVO) har vurdert prosjektet, og finner at behandlingen av personopplysningene vil være regulert av § 7-12 i Personopplysningsforskriften og hjemlet etter Helsepersonelloven § 26.

PVO forutsetter at prosjektet gjennomføres i tråd med de opplysningene som er gitt, samt i henhold til Personopplysningsloven og Helseregisterloven med forskrifter. Videre forutsettes det at data anonymiseres etter prosjektavslutning ved at kodelista slettes.

PVO har på bakgrunn av og tilsendte meldeskjema med vedlegg registrert prosjektet og opprettet et eget område (mappe) på <u>\\hn.helsenord.no\UNN-avdelinger\felles.avd\forskning</u> (o:\) med navn 0707 hvor all data i forbindelse med prosjektet skal lagres. I tillegg er det opprettet et område på <u>\\hn.helsenord.no\UNN-</u> avdelinger\felles.avd\forskning\key med navn **0707N** hvor nøkkelfil skal oppbevares. Tilgang til dette området er begrenset til kun å omfatte prosjektleder og den som prosjektleder definerer. PVO vil ha tilgang til området.

PVO gjør oppmerksom på at dersom registeret skal brukes til annet formål enn det som er nevnt i meldingen, må dette meldes særskilt.

| Postadresse: | Avdeling: | Kvalitets- og utviklingssenteret | Telefon: | 07766 |
|--------------|-------------|--|------------|--------------------------|
| UNN HF | Besøksadr.: | | Internett: | www.unn.no |
| 9038 TROMSØ | Fakturaadr: | UNN HF, c/o Fakturamottak, Postboks 3232, 7439 Trondheim | E-post: | personvernombudet@unn.no |

PVO skal ha melding når registeret er slettet. PVO skal også ha melding dersom registeret ikke er slettet eller ikke ferdig behandlet innen 3 år.

Med hjemmel i Forskrift om behandling av personopplysninger § 7-12 godkjenner PVO at behandlingen kan iverksettes.

Med vennlig hilsen

UNIVERSITETSSYKEHUSET NORD-NORGE HF

PVO-teamet e.f.

Kopi: Klinikksjef Bjørn-Yngvar Nordvåg

Summary of Quality of Central References

| Referanse: | | | Design: Oversiktsartikkel | |
|--|---|--|---|---|
| | L, et al. Surgical Management of D | Dokumentasjonsnivå | lb | |
| Sciatic Nerve Entrapment | : A Systematic Review. Arthroscop | Grade: | Moderate to high | |
| Formål | Materiale og metode | Materiale og metode Resultater | | rer |
| To assess the causes, surgical indications, patient reported clinical outcomes, and complications in patients with deep gluteal syndrome causing sciatic nerve entrapment. Konklusjon Although most of the studies identified were case series and reports, the results consistently showed improvement in pain and a low incidence of complications, particularly for endoscopic procedures. These findings lend credence to surgical management as a viable option for buttock pain caused by deep gluteal syndrome and warrant further investigation Land Canada År data innsamling 2017 | Three databases (PubMed, Ovid [MEDLINE], and Embase) were searched by 2 reviewers independently from database inception until September 7, 2016. The inclusion criteria were studies reporting on both arthroscopic and open surgery and those with Level I to IV evidence. Systematic reviews, conference abstracts, book chapters, and technical reports with no outcome data were excluded. The methodologic quality of the studies was assessed with the MINORS (Methodological Index for Non-randomized Studies) tool. | which 28 (481 patients; mean age, 48 years) were included for assessment. Of the studies, 24 were graded as Level IV, 3 as Level III, and 1 as Level II. The most commonly identified causes were iatrogenic (30%), piriformis syndrome (26%), trauma (15%), and non-piriformis (hamstring, obturator internus) muscle pathology (14%). The decision to pursue surgical management was made based on clinical findings and diagnostic investigations alone in 50% of studies, whereas surgical release was attempted only after failed conservative management in the other 50%. Outcomes were positive, with an improvement in pain at final follow-up (mean, 23 months) reported in all 28 studies. The incidence of complications from these procedures was low: Fewer than 1% and 8% of open surgical procedures and 0% and fewer than 1% of endoscopic procedures resulted in major (deep | Sjekkliste: Er formålet med artikkelen klart for Søkte forfatterne etter relevante s Er det sannsynlig at alle relevante Most likely Ble kvaliteten på de inkluderte stu vurdert? Yes Hvis resultatene er slått sammen dette fornuftig og forsvarlig? Not r Hva er resultatene? The results a descriptive manner. Decrease in p a decrease of mean from preoper Hvor presise er resultatene? The mean without SD and in percenta Kan resultatene overføres til prak Ble alle viktige utfallsmål vurdert? function were not done Veier fordelene opp for ulemper or Styrke Undisclosed Svakhet Limited by the quantity and qua included. Heterogeneity with respect to su adjunctive treatment and evaluated outco reported outcomes. The surgical learning endoscopic release of the sciatic nerve | studier? Yes e studier ble funnet? udiene tilstrekkelig i en metaanalyse, er relevant re presented in a pain are described as rative to follow-up. results are given in ge. sis? Yes ? Assesment of og kostnader? Yes ality of the studies urgical management, mes. Lack of patient- |

| Referanse: | | | Design: RCT | |
|---|---|--|---|--|
| Meknas K, Kartus J, Letto JI, et al. Surgical release of the internal obturator tendon for the treatment | | | Dokumentasjonsnivå | lb |
| of retro-trochanteric pain syndrome: a prospective randomized study, with long-term follow-up. Knee Surg Sports Traumatol Arthrosc 2009; 17: 1249-56. | | | Grade: | Low to moderate |
| Formål | Materiale og metode | Resultater | Diskusjon/kommentarer | |
| Evaluate surgical release of the internal obturator tendon as a treatment for retro- trochanteric pain syndrome. Konklusjon Surgical release of the internal obturator muscle resulted in long-term decrease in pain in patients with retro-trochanteric pain syndrome. Land Norway År data innsamling 2009 | Twelve patients with clinical signs of retro-trochanteric pain syndrome were randomized to either operative treatment or a control group. Six patients were operated on with sectioning of the tendon to the internal obturator near its insertion to the trochanter major | There was no significant pain decrease in either group at 6 months. However, at 8 years, the decrease in pain was significant in the surgical group ($P < 0.03$) but not in the control group. Three patients in the surgical group who needed pain medication with opioids preoperatively managed without such drugs at 8 years. Two patients were working half time at the 8 year follow-up. Before the start of the study the patients had been out of work for 3 and 10 years, respectively. At inclusion 4/12 patients had minor degenerative changes at the L3-L5 level as seen on computerized tomography or magnetic resonance imaging. At 8 years, the corresponding change was found in 7/9 patients ($P = 0.025$). | Sjekkliste: Er formålet med studien klart fo Ble utvalget fordelt til de ulike g randiseringsprose-dyre? Yes Ble alle deltakerne gjort rede fo studien? Yes Ble deltakere/studiepersonell bl gruppetilhørighet? Not reported blinded. Var guppene like ved starten? Yes Ble gruppene behandlet likt? Yes Ble alle deltakere gjort rede for the surgical group and 1/6 drop Hva er resultatene? The most in were controlled, and the follow- enough. The effect is decrease Kan resultatene overføres til pra Ble alle utfallsmål vurdert? Yes Er fordelene verdt ulemper/kost Styrke: Independent examiners for lor radiological follow-up Svakhet: Few patients, not enough po difference between groups | ruppene med or på slutten av lindet mht l, judged as not Yes es ? Yes. 1/3 dropout in yout in the controlgroup mportant variables of mean pain. aksis. Yes tnader? Yes ng-term and |

| Referanse: | | | Design: Pasientserie | |
|--|--|---|---|--|
| Han SK, Kim YS, Kim TH, et al. Surgical Treatment of Piriformis Syndrome. Clin Orthop Surg 2017; 9: | | Dokumentasjonsnivå | III | |
| 136-44. | | | Grade: | Low |
| Formål | Materiale og metode | Resultater | Diskusjon/komme | ntarer |
| This study analyzes the diagnostic methods and efficacy of conservative and surgical treatments for piriformis syndrome Piriformis syndrome is thought to be an exclusively clinical diagnosis, and if the diagnosis is performed correctly, surgery can be a good treatment option in patients with refractory sciatica despite appropriate conservative treatments Land Korea Ár data innsamling 2017 | From March 2006 to February 2013, we retrospectively reviewed 239 patients who were diagnosed with PS and screened them for eligibility according to our inclusion/exclusion criteria. All patients underwent various conservative treatments initially including activity modification, medications, physical therapy, local steroid injections into the piriformis muscle, and extracorporeal shock wave therapy for at least 3 months. We resected the piriformis muscle with/without neurolysis of the sciatic nerve in 12 patients who had intractable sciatica despite conservative treatment at least for 3 months. The average age of the patients (4 males and 8 females) was 61 years (range, 45 to 71 years). The average duration of symptoms before surgery was 22.1 months (range, 4 to 72 months), and the mean follow-up period was 22.7 months (range, 12 to 43 months). We evaluated the degree of pain and recorded the responses using a visual analog scale (VAS) preoperatively and 3 days and 12 months postoperatively. | Buttock pain was more improved than sciatica with various conservative treatments. ESWT was the most effective conservative treatment relieving pain. Compared with preoperatively, the VAS score was significantly decreased from a mean of 9.0 to 4.0 after the operation, and 3.1 at 12 months. Overall, satisfactory results were obtained in 10 patients (83%) after surgery. | Sjekkliste: Var studien basert på et tilfeld pasientgruppe? Yes Var det sikret at utvalget ikke Var inklusjonskriteriene for ut Er svarprosenten høy nok? All patients were assessed Var alle pasientene i utvalget sykdom? Yes Var oppfølgningen tilstrekkelig synliggjøre endepunktene? It to walk and sit are assessed. a longer follow-up time. Ble objektive kriterier benyttel endepunktene? Yes Ved sammenlikninger av pasi tilstrekkelig beskrevet og prog fordeling beskrevet? Not relev Var registreringen av data progretorspective Styrke Undisclosed | var selektert? Yes valget klart definert? Yes i samme stadium av g (type/omfang/tid) for å is desirable that ability It is also desirable with t for å vurdere/validere fentserier, er seriene gnostiske faktorers vant |

| Referanse: | | | Design: Pasientserier | |
|---|---|------------|---|--|
| Martin HD, Shears SA, Johnson JC, et al. The endoscopic treatment of sciatic nerve entrapment/deep gluteal syndrome. Arthroscopy 2011; 27: 172-81. | | | Dokumentasjonsnivå III | |
| | | | Grade: Low | |
| Formål | Materiale og metode | Resultater | Diskusjon/kommentarer | |
| The purpose of this study was to investigate the historical, clinical, and radiographic presentation of deep gluteal syndrome (DGS) patients, describe the endoscopic anatomy associated with DGS, and assess the effectiveness of endoscopic surgical decompression for DGS. Konklusjon Endoscopic decompression of the sciatic nerve appears useful in improving function and diminishing hip pain in sciatic nerve entrapment/DGS. Land United States År data innsamling 2010 | Sciatic nerve entrapment was diagnosed in 35 patients (28 women and 7 men). Portals for inspection of the posterior peritrochanteric space (subgluteal space) of the hip were used as well as an auxiliary posterolateral portal. Patients were treated with sciatic nerve decompression by resection of fibrovascular scar bands, piriformis tendon release, obturator internus, or quadratus femoris or by hamstring tendon scarring. Postoperative outcomes were evaluated with the modified Harris Hip Score (MHHS), verbal analog scale (VAS) pain score, and a questionnaire related specifically to sciatic hip pain. | | Sjekkliste: Var studien basert på et tilfeldig utvalg fra en e pasientgruppe? Yes Var det sikret at utvalget ikke var selektert? Yee Var inklusjonskriteriene for utvalget klart define Er svarprosenten høy nok? For the Benson questionary the rate was 66%, for the other va 100% Var alle pasientene i utvalget i samme stadium sykdom? Yes Var oppfølgningen tilstrekkelig (type/omfang/tid synliggjøre endepunktene? A little to short folle time Ble objektive kriterier benyttet for å vurdere/va endepunktene? Yes Ved sammenlikninger av pasientserier, er serie tilstrekkelig beskrevet og prognostiske faktorer fordeling beskrevet? Not relevant Var registreringen av data prospektiv? Not cleat likely Styrke Undisclosed Svakhet Experience were a factor in preoperative evand treatment. The Benson criteria data were only obta a subset of patients. | es ert? Yes riables n av d) for å ow-up lidere ene rs ar, but aluatior |

| Referanse: | | | Design: Kasuskontroll | |
|--|--|--|--|--|
| Furia JP, Rompe JD, Maffulli N. Low-energy extracorporeal shock wave therapy as a treatment for greater trochanteric pain syndrome. Am J Sports Med 2009; 37: 1806-13. | | | Dokumentasjonsnivå III | |
| | | | Grade: Low | |
| Formål | Materiale og metode | Resultater | Diskusjon/kommentarer | |
| The aim of this study was to determine whether low- energy SWT is a safe and effective management modality for chronic GTPS | Thirty-three patients with chronic greater trochanteric pain syndrome received low-energy shock wave therapy (2000 shocks; 4 bars of pressure, equal to 0.18 mJ/mm2; total energy flux density, 360 mJ/mm2). Thirty-three patients with chronic greater trochanteric pain syndrome were not treated with shock wave therapy but received additional forms of nonoperative therapy (control). All shock wave therapy procedures were performed without anesthesia. Evaluation was by change in visual analog score, Harris hip score, and Roles and Maudsley score. | Mean pretreatment visual analog scores for the control and shock wave therapy groups were 8.5 and 8.5, respectively. One, 3, and 12 months after treatment, the mean visual analog score for the control and shock wave therapy groups were 7.6 and 5.1 (P < .001), 7 and 3.7 (P < .001), and 6.3 and 2.7 (P < .001), respectively. One, 3, and 12 months after treatment, mean Harris hip scores for the control and shock wave therapy groups were 54.4 and 69.8 (P < .001), 56.9 and 74.8 (P < .001), and 57.6 and 79.9 (P < .001), respectively. At final follow-up, the number of excellent, good, fair, and poor results for the shock wave therapy and control groups were 10 and 0 (P < .001), 16 and 12 (P < .001), 4 and 13 (P < .001), and 3 and 8 (P < .001), respectively. Chi-square analysis showed the percentage of patients with excellent (1) or good (2) Roles and Maudsley scores (ie, successful results) 12 months after treatment was statistically greater in the shock wave therapy than in the control group (P < .001). | Sjekkliste: Var kasus-kontrollgruppene rekrutert fra sammenliknbare befolkningsgrupper? Yes Er gruppene sammenliknbare i forhold til viktige bakgrunnsfaktorer? Yes Er kasusgruppens tilstand tilstrekkelig beskrevet/diagnosen validert? Yes Er kontrollgruppen fri for den aktuelle tilstanden/sykdommer | |
| Konklusjon Shock wave therapy is an effective treatment for greater trochanteric pain syndrome | | | No, it should not be either. Har forfatterne tatt hensyn til viktige konfunderende faktorer i design/analyse? Yes Er eksponering for fare/skade/tiltak målt og gradert likt i gruppene? Yes Var den som målte eksposisjon blindet mht hvem som var kasus/kontroll? Not likely Var responsraten tilstrekkelig i begge grupper? Yes | |
| United States År data innsamling 2009 | | | Styrke There was not given local anaestatics before/unde the procedure of ESWT Svakhet Short follow-up time, no randomization, no placebo group, MRI was not performed for each patient | |