

TITLE PAGE

Official Title: To compare thread technique versus aspiration plus steroid injection of wrist ganglion in terms of frequency of recurrence.

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ABSTRACT

Background: Ganglion is one the most common wrist soft tissue tumors and treatment strategies are aiming to reduce the frequency of recurrence.

Objectives: To compare the recurrence of wrist ganglion following thread technique versus aspiration plus steroid injection.

Study design: Randomized controlled trial

Place and duration of study: Department of Surgery. HIT Hospital, Taxila from June 2020 to December 2020.

Materials and Methods: Sixty patients were randomized into two equal groups A and B after clinical diagnosis of wrist ganglion. Informed written consent was obtained after informing all pros and cons of the procedure. The thread technique was done in group A while in group B methyl prednisolone acetate 40 mg/ml was injected after aspiration. The patients were followed 2 weeks, 6 weeks, 3 months, and 6 months. The clinical examination was done to see the possible recurrence.

Results: The mean age of the participants was 29.30 ± 6.0 years. Mean duration of ganglia was 19.33 ± 8.35 months. The location of ganglia was 37 (61.7%) dorsal and 23 (38.3%) volar. The male to female ratio was 22 (36.7%): 38 (63.3%). Collectively, the frequency of recurrence was 6 (10%), 10 (16.7%), 12 (20%) and 16 (26.7%) at 2 weeks, 6 weeks, 3 months, and 8 months respectively.

There was no difference between groups A and B in terms of age, gender, location, and duration of disease (p values 0.401, 0.592, 0.791, 0.783 respectively). The frequency of recurrence was significantly different among groups at and 6 months i.e. 12 (40.0%) in group A versus 4 (13.3%) in group B (p value 0.020).

Conclusion: The thread technique of wrist ganglia is superior to steroid injection in terms of recurrence. The RCTs with larger sample size and prolonged follow-up would provide more insight into this subject.

Key words: Cyst, Ganglion, Thread technique, Wrist swelling,

INTRODUCTION

Ganglia is the commonest cause of referral for upper extremity soft tissue tumors. More than 50% of referrals belong to this category. Ganglion originated from joint capsule or tendon sheaths. The most common site is wrist followed by the vicinity of interphalangeal joints. The dorsal ganglia mostly originate from scapho-lunate interosseous ligament while volar may arise from radio-scaphoid joint or scapho-trapezoid joint.^{1, 2} The most common presentation is painless lump at abovementioned areas. The pain may arise when the ganglia exert pressure effects during movements. The diagnosis is clinical in most cases and additional laboratory, or radiological investigations are often not helpful.^{2, 3}

The treatment of ganglia is mainly sought out due to pain or cosmetic reasons. Management is tailored accordingly ranging from simple reassurance to surgical excision with in between options of aspiration with and without steroid injection, hyaluronidase injection and thread or seton insertion. The surgical excision may be orthoscopic as well.^{4, 5} The aspiration and steroid injection may be cost effective but is associated with skin pigmentation, atrophic changes, and increased chances of recurrence.⁶ Surgical excision is associated with operative cost, infections and possible chances of nerve, tendon, or joint damage. The thread technique has been seen in some early research but to some extent has been ignored irrespective of the fact that it is cost effective and has comparable outcomes. The recurrence is common with all the current procedures.^{7, 8} A study by Zangana, M. and K. Dizaye found that recurrence of 4% was observed in threading technique while 43% in aspiration plus steroid injection ($p < 0.001$).⁹

We conducted this study to determine the frequency of recurrence of wrist ganglia between threading technique and aspiration plus steroid injection. Both these procedures are being practiced as outpatient procedures in our setup. There is paucity in local and international literature regarding this specific subject. The result of our study would provide us with better insight into this subject and will leave us with a better choice to treat wrist ganglia.

METHODS AND MATERIALS

This randomized controlled trial was conducted at HIT hospital Taxila from January 2020 to June 2020 for period of one year with clinical diagnosis of wrist ganglion. This study was conducted in accordance with ethical standards and principles. Institutional Review Board (IRB) or Ethics Committee approval was obtained prior to the commencement of the research (Reference number: ERC/19/15(b)). Informed consent was acquired from all participants involved in the study. The research was conducted with respect for participant privacy, confidentiality, and autonomy. The trial was registered on clinicaltrials.gov (NCT). The sample size of 60 patients (30 in each group) was calculated by taking recurrence rates of 4% and 43% for threading technique and aspiration plus steroid injection respectively from a study.⁹ The level of significance was 5% and power of test was 90%. The age range of 18 to 50 years from both gender groups with clinical and radiological diagnosis of wrist ganglion was included. Patients with history of previous invasive treatments, compound ganglion, diabetes mellitus, bleeding diathesis, immunosuppression or rheumatoid arthritis were excluded from the study. The sampling technique was consecutive non-probability. Randomization of patients was done into two equal groups by computer generated numbers. In group A, the aspiration of ganglion was done by 18G needle attached to a 10 ml syringe. After full aspiration, methylprednisolone (40 mg/ml) was injected into the cavity. In group B, the silk suture size 1 was passed horizontally through the ganglion and tied over sterile gauze. The evacuation of mucinous contents was done manually, and patients were instructed to do manual massage three times daily for 7 days. The thread was removed after 2 weeks or when only serosanguinous discharge was observed at the entry points of thread. Both procedures were done with full aseptic measures and under local anesthesia of 1% lignocaine. The patients were followed in OPD after 2 weeks, 6 weeks, 3 months, and 6 months. The recurrence was noted down on specially designed proforma for study.

The data was analyzed by Statistical Package for Social Science (SPSS) version 25 registered for Microsoft windows. The quantitative variables like age and duration of disease were expressed by mean and standard deviation. The qualitative variables like gender and recurrence at follow up visits were expressed as frequency and proportions. Both groups A and B were compared among each other in terms of recurrence at 2 week, 6 weeks, 3 months, and 6 months by Chi Square test. P value of <0.05 was considered statistically significant.

RESULTS

We aimed at our target sample size of 60 patients (30 in each group). The total patients selected were 73 out of which 13 lost follow up. The mean age of the participants was 29.30 ± 6.0 years. Mean duration of symptoms was 19.33 ± 8.35 months. The location of ganglia was 37 (61.7%) dorsal and 23 (38.3%) volar. The male to female ratio was 22 (36.7%): 38 (63.3%). Collectively, the frequency of recurrence was 6 (10%), 10 (16.7%), 12 (20%) and 16 (26.7%) at 2 weeks, 6 weeks, 3 months, and 8 months respectively.

There was no difference between groups A and B in terms of age, gender, location, and duration of disease (p values 0.401, 0.592, 0.791, 0.783 respectively, Table I). The frequency of recurrence changed over subsequent follow up visits. The frequency of recurrence was significantly different among groups at 6 weeks and 6 months (p values 0.038 and 0.020, Table II). The recurrence was different at 2 weeks and 3 months' time but fell below the required level of significance (p values 0.085 and 0.053 respectively). There was no difference gender and location groups in terms of recurrence at six months (p value 0.936 and 0.603).

DISCUSSION

Ganglion cysts are synovial cysts which are filled with mucinous contents. These are most common in upper extremity. The diagnosis is mainly clinical with few clinical signs like Tadpole sign. Occasionally radiological evaluation is required. The exact etiology is unknown but microtrauma leading to mucinous degeneration is considered responsible for it. Female gender is more prone to have ganglia as well as patients with wrist hyperlaxity. About 60-70% of the ganglion cysts are found in dorsal wrist area.^{10, 11} Dorsal ganglia are commonly located superficial to scapholunate ligament while dorsal cysts are located between the radial artery and flexor carpi radialis.¹² Main reasons to seek medical attention is pain, tenderness, and cosmetic concerns. Both surgical and non-surgical options are available, but pros and cons should be clearly explained to patients.^{2, 13}

Simple reassurance is enough for some patients as 58% ganglion cysts resolve spontaneously over time. The symptomatic treatment is enough for some patients. Aspiration alone of wrist ganglia has high frequency of recurrence and injection of steroids after aspiration improved outcomes. The results in difference studies are variable after steroid injection.^{10, 14} The recurrence in my study was 40% after steroid injection. The difference may arise since in our study we used 18G single needle to aspirate and inject while above study used double 18G lines i.e. distal for aspiration and proximal for injection.

The surgical excision has been traditionally advocated due to increased patient's satisfaction and decreased frequency on recurrence in short and long term follow up as compared to aspiration alone or with steroid injection. Cluts, L. M. and J. R. Fowler had recurrence of 3.8% after surgical excision in a short term follow up. The recurrence is associated with surgeon's expertise and male gender.⁸ A study with long term follow up of 5 years showed that recurrence after surgical excision may reach up to 8%. The location of ganglion has no impact on the recurrence. The surgical excision has some concerns over it due to the proximity of neurovascular elements in excision of volar ganglia.¹⁵ The surgery of

dorsal ganglia is prone to develop unsightly scar that's provide the opportunity of arthroscopic procedures to get in.¹⁶

A study by Zangana, M. and K. Dizaye compared thread technique with traditional methods for treatment of wrist ganglia. With a sample size of 785 patients with dorsal ganglia, three methods i.e. surgical excision, aspiration and steroid injection, thread technique were compared among each other. At the end of six months, recurrence of 24%, 43% and 4% was noted in surgical excision, aspiration plus steroid injection and thread technique respectively.⁹ A recent study by Chaudhary, S., et al. (2021) on thread technique demonstrated that after six months of follow up, the recurrence rate was 9%. Most of the patients were satisfied and the procedure was almost painless without any significant complications. The technique was a bit modified in this study as the silk suture was passed over a sterile gauze to keep the entry and exit sites of silk relatively wide enough to permit early flow of thick mucinous contents. The recurrence was observed in cases in which the evacuation of entire contents was not possible.⁷ Another recent study found the recurrence after threading technique as 3.8%.⁴ The study by Saeed, B., et al. included a total sample of 204 patients, with mean age of 29.26 ± 8.16 years. Dorsal wrist ganglions accounted for 160 cases (78.43%), whereas volar ganglions were identified in 44 cases (21.57%). The mean duration of symptoms was 10.07 ± 3.74 months. Recurrence rates showed no significant difference between the groups, with threading group recording 7 recurrences (4.35%) and surgical excision group 2 recurrences (4.65%) ($p = 0.931$).¹⁷ The use of thread other than silk have been studied also which show similar recurrence rates as compared to silk e.g., nylon showed 6.6% recurrence rate.¹⁸ A prospective study evaluated 30 patients with dorsal wrist ganglia larger than 5 mm treated at the General Surgery outpatient department of Government Hospital Sarwal, Jammu, India. The mean age of the patients was 44.29 ± 2.59 years, with the majority being female, and the primary

reason for intervention was cosmesis. The study achieved a cure rate of 93.3%, with a recurrence rate of 6.7% (2 cases).¹⁹

My study targeted a sample size of 60 patients, with 30 in each group. A total of 73 patients were initially selected, but 13 were lost to follow-up. The mean age of participants was 29.30 ± 6.0 years, and the average symptom duration was 19.33 ± 8.35 months. Ganglia were located dorsally in 61.7% of cases (37 patients) and volarly in 38.3% (23 patients), with a male-to-female ratio of 36.7% to 63.3%. Recurrence rates were 10% at 2 weeks, 16.7% at 6 weeks, 20% at 3 months, and 26.7% at 8 months. The recurrence rates differed significantly between groups at 6 weeks ($p = 0.038$) and 6 months ($p = 0.020$). While differences at 2 weeks and 3 months were noted, they were not statistically significant ($p = 0.085$ and 0.053 , respectively). Gender and location showed no association with recurrence at six months ($p = 0.936$ and 0.603). Shakya et al. describe the "Triple Technique," a new outpatient procedure for treating dorsal wrist ganglions, which combines aspiration, steroid injection, and trans fixation with silk suture for 3 weeks. The study included 83 patients with a mean age of 31.7 ± 12.4 years with overall success rate of 95.2%. The Triple Technique is an effective and safe method, with a recurrence rate of less than 5% at 2 years.²⁰

CONCLUSION

The threading technique of wrist ganglia is superior to steroid injection in terms of recurrence rate in short term follow up. The RCTs with larger sample size and prolonged follow-up would provide more insight into this subject.

TABLES

Parameter	Group A (Steroid group) (n=30)	Group B (Thread group) (n=30)	P value
Age (years)	29.83 ± 6.21	28.37 ± 7.17	0.401 [*]
Gender (M/F)	10/20	12/18	0.592 [†]
Location (Dorsal/Volar)	19/11	18/12	0.791 [†]
Duration of symptoms (months)	19.03 ± 8.10	19.63 ± 8.73	0.783 [*]

Table I. Age, gender, and duration among groups

^{*} Independent sample t test

[†] Chi square test

Frequency of recurrence	Group A (Steroid group) (n=30)	Group B (Thread group) (n=30)	P value [‡]
After 2 weeks	5 (16.7%)	1 (3.3%)	0.085
After 6 weeks	8 (26.7%)	2 (6.7%)	0.038
After 3 months	9 (30.0%)	3 (10.0%)	0.053
After 6 months	12 (40.0%)	4 (13.3%)	0.020

Table II. Recurrence among groups

[‡] Chi square test

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CONSENT FORM

Project Title	To compare thread technique versus aspiration plus steroid injection of wrist ganglion in terms of frequency of recurrence
Principal investigator	Dr. Abdul Basit
Research team contact	+923002166598
Importance of study / purpose of study	The study intends to know to better technique to reduce the recurrence of wrist ganglion.
Description of study	Methodology will be explained verbally
Confidentiality	Names, contact information or any other personal information of the patients will be held in strict confidentiality. The results will be reported in aggregate form only, and will not be identified individually
Authorization	
<ul style="list-style-type: none"> I, ----- W/O ----- ID NO----- -hereby fully agree to contribute to the above-mentioned study and future related studies on these sample I was given ample time to think and discuss the study I understand that this study is designed to add to the medical knowledge I have been informed about the nature of the procedure and the possible risk (s) discomfort(s) involved I had the opportunity to ask any questions about the study and I agree to give my consent as requested by Dr. Abdul Basit (the researcher). I have also been informed about my explicit right to withdraw from the study at any time if I want to I have no objection in case the data obtained from me and my investigations (s) is published in a research journal maintaining confidentiality. I have also been conveyed that my participation / non-participation will not affect my treatment (if applicable) 	
Patients' name:	Signature:
Researcher name:	Signature: