INTRARTICULAR ANALGESICS FOLLOWING SHOULDER ARTHROSCOPY: COMPARISON OF ROPIVACAINE/DEXAMETHASONE WITH ROPIVACAINE

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ABSTRACT: INTRODUCTION: Shoulder arthroscopy is a common orthopedics procedure performed on day-case basis. Adequate pain relief reduces surgical stress response, patient's morbidity and improves postoperative recovery and rehabilitation. Various drugs have been tried intra-articularly to provide postoperative analgesia. **PURPOSE:** We studied analgesic effect of dexamethasone 16mg (4ml) with ropivacaine and compared it with ropivacaine intra-articularly in shoulder arthroscopic procedures in search of the ideal analgesic combination. METHODS: A Prospective Multicenter Double Blind study on 60 patients undergoing arthroscopic shoulder surgery from July'13- April'14. Patients were assigned into 3 groups randomly - Group I (20 ml normal saline), Group II (20 ml 0.2% ropivacaine) and Group III (16 ml 0.2% of ropivacaine & dexamethasone- 4 ml containing 16 mg. VARIABLES ASSESSED: Analgesic effect (VAS Score), time to first postoperative analgesic request, Analgesic used during first 24 hours. **RESULTS:** Group III had significant low pain scores for 1st20 hours as compared to Group II and Group I. Time to first analgesic requirement was longest in Group III (1356.2±193.10mins) (p<0.01). Intensity of pain &Total analgesic requirement was significantly less in Group III (38.2±27.83 mg)(p<0.01) in comparison to Group II and I. No significant side-effects were noted. **CONCLUSION:** A16 mg (4ml) dosage of Dexamethasone is safe, cost effective and free from relative side effects, has a better patient compliance in terms of post-operative pain, need for analgesia and should be used routinely in arthroscopic shoulder surgeries. Helps in the recovery of patients to the pre-operative level.

KEYWORDS: Dexamethasone, Ropivacaine, pain relief, intra-articular, arthroscopic, shoulder surgery.

INTRODUCTION: Shoulder surgery can be very painful and interscalene brachial plexus block is the gold standard in the management of acute pain after shoulder surgery. Increasingly, trend is shifting towards day care surgeries especially in arthroscopic and mini-open shoulder procedures¹ to enhance the patient compliance and facilitate early return to home. However, these surgeries evoke different levels of pain which at times can be unbearable depending on the patient's pain tolerance. Post-operative pain has negative impact on patient's psychology, mobilisation and rehabilitation which may lead to a prolonged hospital stay² and affect the prognosis. Adequate pain relief reduces the surgical stress response and improves postoperative recovery and rehabilitation.²

There has always been a search for a simple method for providing postoperative analgesia in these patients that have a prolonged duration of action, easy to administer and should be without any serious side effects. Utilizing the peripheral receptors for postoperative pain management is an important mode of such an approach. The intra-articular route of drug administration utilises the

peripheral receptors and administration of local anaesthetics through this route is routinely done after arthroscopic knee surgery. In shoulder procedures, intrarticular analgesics are not used frequently and the ideal analgesic has not been defined.

Local anaesthetics such as bupivacaine, ropivacaine, opioids like morphine, magnesium sulphate have been used intra-articularly in shoulder arthroscopy with variable duration of analgesia.³⁻⁵ To our knowledge, effect of Intrarticular Dexamethasone in shoulder arthroscopic procedures has been reported in very few studies. We performed a Multicentre Study to study the effects of intrarticular dexamethasone in a double blind, randomised manner in arthroscopic shoulder procedures.

MATERIAL & METHODS: After clearance by the local research committee, 60 candidates for elective shoulder arthroscopy under general anesthesia were subjected to the study in this Multicenter prospective double-blind trial from July'13 to April'14 conducted at Hi- Tech Medical College and Sparsh Hospital and Critical Care Unit after they declared their consent to participate in this study.

INCLUSION CRITERIA: Age of 15–60 years, Male/Female non-addicted patients, no history of mental illnesses, no history of allergy to dexamethasone or ropivacaine, not having renal and liver diseases and (ASA) class I and II, Being operated under general anaesthesia for elective shoulder arthroscopic surgeries like diagnostic arthroscopy, Rotator cuff repair, Bicipital Tenodesis, SLAP tear, Stiff shoulder release, Bankart's lesion etc.

EXCLUSION CRITERIA: Patient refusal, any previous surgery of shoulder, any known allergy or contraindication to ropivacaine, or dexamethasone, pregnancy, lactating mothers and children, hepatic, renal or cardiopulmonary abnormality, alcoholism, diabetes, long-term analgesic therapy, bleeding diathesis, coagulopathies, local skin site infections, hypertension treated with a-methyldopa, clonidine or b-adrenergic blockers, or if they had used opioid or non-opioid analgesics within the previous 24 h or had any contraindication to the study drugs were excluded from the study.

VARIABLES ASSESSED: Post-operative Analgesic effect (VAS Score) at 1sthr, 3rd hr, 6th hr, 12th hr, 18th hr, 24th hr, Time to first postoperative analgesic request, Analgesic used during first 24 hours.

The randomization was performed according to numbers generated by a computer and a person unaware of the study objectives sealed the obtained codes in secure envelopes and then the envelopes were given to one of the researchers who had no role in the treatment or evaluation. Afterwards, the researcher provided a syringe containing the solution based on the confidential codes and gave it to the physician to inject. In the preoperative visit, the visual analogue scale (VAS) with a 10 cm length was fully explained to the patient; based on this scale, zero indicates "lack of pain", and ten signifies "unbearable pain" and the patients were enquired about any history of drug allergy, previous operations, or prolonged drug treatment.

The night before the surgery, all the patients received oral Alprazolam 0.25 mg as premedication, and were NPO 8 h before surgery. Before operation, baseline heart rate (HR), mean arterial pressure (MAP), and VAS were recorded in each patient. On the operation table, routine monitoring (5 leads ECG, transcutaneous pulse oximetry, non-invasive blood pressure) were started and baseline vital parameters like heart rate (HR), blood pressure (systolic, diastolic and mean) and

arterial oxygen saturation (SpO2) were recorded. An intravenous line was secured. The anesthetic technique was standardized for all patients. After placement of routine monitors, all operations were performed under general anesthesia. Syringes containing 20 ml aqueous solutions of either normal saline or ropivacaine or 16 ml ropivacaine with dexamethasone 4ml (16mg) were used. Ropivacaine (ROPIN0.2%- 2mg/ml; NEON) and Dexamethasone (DEXONA-4mg/ml: ZYDUS) were used in the study. At end of surgery, 15 ml of test solution was injected intra-articularly and 5 ml in subacromial space by the orthopedic surgeon, sterile compression bandage applied.

Patients were transferred to post anaesthesia care unit following surgery. Pain value was determined and recorded based on VAS (Where 0 = no pain and 10 = worst possible) and vital parameters like HR, MAP were recorded at 1,3,6,12,18, and 24 hr. after operation, Diclofenac sodium (75 mg) was administered I.V. as an analgesic supplement if the recorded VAS pain score was> 4 and was repeated every 8 h if required. Tramadol 50 mg I.V. was used as a rescue analgesic if the patients continued to have pain after diclofenac administration. The time to the first analgesic requirement and the total diclofenac use during the first 24 h after operation were also recorded. Side-effects such as nausea, vomiting, bradycardia (Defined as HR, 45 beats min.), and hypotension (defined as reduction of MAP.25% of baseline) were recorded. All data were collected by an observer who was unaware of patients' group assignment.

GROUP I - (Control group) received 20 ml saline.

GROUP II- Received 20 ml (0.2%) ropivacaine hydrochloride.

GROUP III- Received 16ml (0.2%) ropivacaine and 4ml Dexamethasone (16 mg).

RESULTS: Out of 60 patients, male patients (42) dominated the groups. As regards the demographic characteristics (see Table 1), there was no significant differences in the mean age, weight of the patients and duration of surgery. No side-effects were reported during the first 24 hour after surgery. Mean Arterial pressure and heart rate did not change significantly:

- The operative arthroscopic procedures were comparable in the 3 groups (see Table2).
- VAS scores in Group III at 3rdhr (p<0.01) and at 6thhr (p<0.02) and 12thhr (p<0.05) and 18th (p<0.05) hour was least as compared to group I and II following surgery (see Fig.1).
- No incidence of nausea, vomiting, bradycardia, hypotension or other side-effects requiring intervention was reported in the subjects.



Time to first post-operative analgesia request was longest in Group III (1356.2 ± 193.10 mins) as compared to the group II (433.2 ± 54.3 mins) and group I (311.8 ± 61.56 mins) (p<0.01). Mean Total analgesic consumption in first 24hrs was least in group III (38.2 ± 27.83 mg) followed by group I (221.25 ± 56.93 mg) and group II (153.75 ± 51.5 mg) (p<0.01) (see Table.3).

DISCUSSION: Shoulder arthroscopic surgery can be very painful. Causes of post-operative pain following arthroscopic procedure include irritation of free nerve endings of synovial tissue and joint capsule during surgical excision, extensive resection of bursal tissue, insertion of hardware, bone removal and soft tissue distension from irrigation fluid.¹

Early Successful rehabilitation after arthroscopic shoulder surgery requires the use of effective methods for adequate postoperative pain control and early mobilization. Research has been directed toward developing newer techniques and new doses for increased duration of postoperative analgesia. For postoperative analgesia following knee arthroscopy local anesthetics like lidocaine⁶ and bupivacaine,⁷ opioids likemorphine,⁸ alpha 2 adrenoreceptor agonists like clonidine,⁹ dexmeditomidine,¹⁰ magnesium sulphate,¹¹ dexamethasone¹² have all been tried intra-articularly either as sole agents or in combination, but their role in shoulder arthroscopic procedures has not been reported much.

Though dexamethasone has been used intrarticularly in a dose of 8mg (2ml) following shoulder arthroscopic surgeries with good results, To date, no study has evaluated the analgesic effects in a dosage of 16mg (4ml) in shoulder arthroscopic surgeries which could enhance the post-operative analgesia and the requirement of analgesics post operatively, thus having a better patient compliance as reported in our study.

Dexamethasone was selected because of its highly potent anti-inflammatory property with minimal mineralocorticoid activity and devoid of potential side effects. Steroids also share a block prolonging effect due to their anti-inflammatory potency.^{13,14} The dense and prolonged block in the

dexamethasone group is attributed to the synergistic action with local anesthetic ropivacaine on blockade of nociceptive C-nerve fibers.

Studies report significant pain relief up to 12 hours post shoulder arthroscopy in patients receiving intrarticular injection of 1000mg magnesium sulphate with10ml normal saline but reported side effects like nausea, vomiting in few patients⁴ and upto 10 hours in patients receiving intrarticular ropivacaine with decreased analgesic requirement.³ Whereas we report a significant pain free period of upto 22 hours as was seen in few cases, in patients receiving intrarticular dexamethasone (16mg,4ml) with 16ml of ropivacaine as compared to normal saline and ropivacaine injections alone. Our patients were extremely pleased with the surgery and to our surprise, they did not require analgesic support even upto 24 hours in many cases.

We report a significant prolongation of analgesia and the time to first post-operative analgesic requirement (1356.2 ± 193.10 min p< 0.01), a significant reduction in consumption of analgesic (38.2 ± 27.83 mg p< 0.01) and a significantly lower pain VAS score in the first 24 hours in the intra-articular dexamethasone group which are better as compared to the reported literature. We attribute these results to the new dosage of dexamethasone 16mg (4ml).

A limitation of our study is that we did not measure the plasma concentration of dexamethasone to correlate it with the clinical findings, which may have confirmed the local effects. A 16 mg (4ml) dosage of intrarticular dexamethasone enhanced the postoperative analgesia after arthroscopic shoulder surgery without significant side effects. Thus, 16mg (4ml) can safely and effectively be used in post shoulder arthroscopic procedures.

CONCLUSION: Our results, suggests that our combination of Dexamethasone-16mg(4ml) with ropivacaine, intrarticularly has a superior analgesic efficacy and better postoperative pain relief (VAS) and decreased need of total postoperative analgesia and better patient compliance with no relative side effects. We recommend the use of Dexamethasone 16 mg (4ml) in arthroscopic shoulder surgeries to facilitate early rehabilitation and good functional scores.

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| Variables | Group R(n=20) | Group D1 (n=20) | Group D2 (n=20) |
|-------------------------------|---------------|-----------------|-----------------|
| Age (Years) | 30.8±10.74 | 31.7±13.40 | 32.3±9.17 |
| Gender (M/F) | 14 / 6 | 15 / 5 | 13 / 7 |
| Weight (Kgs) | 63.6±5.44 | 63.9±11.60 | 66.3±6.92 |
| Surgery Duration (minutes) | 93.0±20.02 | 99.0±33.48 | 98.0±28.98 |

Table 1: Patient characteristics of 3 groups (n=20) Data are Mean (range) or Mean (SD)

| Surgical Procedure | Group R (n=20) | Group D1 (n=20) | Group D2 (n=20) | | | |
|---|----------------|-----------------|-----------------|--|--|--|
| Diagnostic arthroscopy | 6 | 5 | 5 | | | |
| Bankarts' Repair | 4 | 5 | 4 | | | |
| Rotator cuff tear repair | 3 | 4 | 3 | | | |
| Stiff shoulder release | 3 | 2 | 4 | | | |
| Repair of SLAP tear | 2 | 2 | 3 | | | |
| Subacromial decompression | 2 | 2 | 1 | | | |
| Table 2: Types of Arthroscopic Procedures undergone by the 3 Groups | | | | | | |

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| | Group I | Group II | Group III | P value |
|---|--------------|-------------|---------------|---------|
| Mean Time to 1 st Post-Operative Analgesic Requirement (mins) | 311.8±61.56 | 433.2±54.3 | 1356.2±193.10 | 0.004 |
| Mean Total Analgesic (Diclofenac) consumption in 24 hours (mg) | 221.25±56.93 | 153.75±51.5 | 38.2±27.83 | 0.007 |

Table 3: Analgesia Duration and total Analgesic Requirement in 24 Hours

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