

A STUDY ON TRANSFORAMINAL BLOCK COMPARISON OF TANSELONE AND DEXAMETHASONE

YUGAL CHANDRAKAR¹, NINJARAO EVANE², AKHILESH YONA^{3*}

¹Department of Anaesthesia, Director and Consultant Soham Hospital, Mahasmund, Chhatisgarh, India. ²Department of Anaesthesia, Shree Gowardhan Critical Care Maternity Trauma Center and Multispeciality Hospital, Betul, Madhya Pradesh, India. ³Department of Anaesthesia, Anaesthesia Specialist (Class-I), DSPM Civil Hospital, Itarsi, Madhya Pradesh, India.

*Corresponding author: Akhilesh Yona; Email: akhileshyona@gmail.com

Received: 02 April 2024, Revised and Accepted: 15 May 2024

ABSTRACT

Objectives: To compare the efficacy and safety of Tanselone and Dexamethasone in TFESIs and provide guidance for their use, particularly for new pain specialists and postgraduate students.

Methods: A prospective, randomized controlled trial was conducted, enrolling 100 patients with spinal pain syndromes randomized to receive either Tanselone or Dexamethasone in TFESIs. Pain intensity scores and functional outcomes were assessed at baseline and follow-up intervals (11). Adverse events related to TFESIs were monitored. Statistical analysis was performed to compare outcomes between the two groups.

Results: Tanselone demonstrated superior efficacy in pain relief and functional improvement compared to Dexamethasone, with patients in the Tanselone group experiencing greater reductions in pain intensity scores and improvements in functional outcomes at all follow-up intervals. However, concerns were raised regarding the potential risk of vascular complications associated with Tanselone's particulate nature. For new pain specialists and postgraduate students, Dexamethasone may be considered a safer alternative to minimize the risk of complications associated with TFESIs (11). A difference which was significant statistically in the Pain intensity score questionnaire (3.73 ± 1.15 in group T, 6.55 ± 0.51 in group Dx) and Oswestry disability index (18.67 ± 7.13 in group T, 35.83 ± 5.10 in group Dx) was found in both but was more in Tanselone group.

Conclusion: By comparing Tanselone and dexamethasone for epidural injection, for the duration of analgesia of pain in lumbar radiculopathy, injection of Tanselone has been found to be more effective than injection of dexamethasone through transforaminal route. Clinicians should weigh the potential benefits of Tanselone's efficacy against its perceived risks and consider using Dexamethasone, especially for novice practitioners, to minimize the risk of complications and ensure procedural safety in patients with spinal pain syndromes.

Keywords: Tanselone, Dexamethasone, Transforaminal epidural steroid injections, Transforaminal block.

© 2024 The Authors. Published by Innovare Academic Sciences Pvt Ltd. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>) DOI: <http://dx.doi.org/10.22159/ajpcr.2024v17i6.51395>. Journal homepage: <https://innovareacademics.in/journals/index.php/ajpcr>

INTRODUCTION

Transforaminal epidural steroid injections (TFESIs) have emerged as a pivotal intervention in the armamentarium for managing various spinal pain conditions, including radicular pain stemming from herniated discs, spinal stenosis, and other degenerative spine disorders [1]. These procedures deliver corticosteroids directly to the affected nerve root, offering targeted relief and reducing inflammation surrounding the spinal nerves [1]. In the realm of TFESIs, the choice of corticosteroid plays a crucial role in determining the efficacy and safety of the intervention [2]. Tanselone and Dexamethasone are two commonly used corticosteroids in clinical practice, each possessing distinct pharmacokinetic and pharmacodynamic properties [2]. While both drugs aim to mitigate inflammation and alleviate pain, their differential characteristics may influence their effectiveness in transforaminal blocks [2]. The rationale for comparing Tanselone and Dexamethasone in this study stems from the need to optimize treatment outcomes and minimize potential risks associated with TFESIs [2]. Despite the widespread use of these corticosteroids, there remains a paucity of comparative studies evaluating their relative efficacy and safety profiles in transforaminal blocks [2]. By conducting a comprehensive comparison of Tanselone and Dexamethasone in transforaminal blocks, this study seeks to address this gap in the literature and provide evidence-based guidance for clinicians in

selecting the most appropriate corticosteroid for individual patients [2]. Through meticulous analysis of pain relief, functional improvement, and adverse event profiles, this investigation aims to inform clinical decision-making and enhance the quality of care for individuals suffering from spinal pain syndromes [2]. Furthermore, elucidating the comparative effectiveness of Tanselone and Dexamethasone in TFESIs holds the potential to refine treatment algorithms, optimize resource utilization, and ultimately improve patient outcomes in the management of spinal pain disorders [2]. As such, this study endeavors to contribute valuable insights to the evolving landscape of interventional pain management, with implications for both clinical practice and future research endeavors [2].

METHODS

The present prospective randomized control study was carried out in the Department of Anesthesia, Mahatma Gandhi Memorial Medical College, Indore from 2018 to 2019, after taking approval from the Institutional Ethical Committee of MGMMC Indore.

Inclusion criteria

The following criteria were included in the study:

- Age between 18 and 80 years,
- Either gender

- Who had failed conservative treatment for lumbar radiculopathy
- Willing for lumbar TFESI for radicular pain in the lumbar region,
- Diagnosis clinically based on pain distribution and compression of the nerve root in magnetic resonance imaging.

Exclusion criteria

The following criteria were excluded from the study as

- Previous lumbar spine surgeries
- Disease of degeneration of spine
- Steroid medication used chronically through oral, peripheral, or epidural route in the previous 3 months
- Allergy to myelographic contrast, steroid, and local anesthetic.

Patients were allocated randomly into two groups of 50 each (group Dx and T) based on a random number table generated through the computer. Group Dx (50 subjects) fluoroscopically guided transforaminal dexamethasone 8 mg epidural steroid injection Group T (50 subjects) - Fluoroscopically guided transforaminal Tanselone 40 mg epidural steroid injection. Informed consent was taken. Before giving epidural injection, the baseline pain score was recorded by Intensity pain questionnaire, and functional assessment was done using the revised Oswestry disability index (RODI) [3].

Sample size calculation

OpenEpi.com was used for the calculation of sample size. Keeping the confidence interval at 95% (α error at 0.05), power at 80%, and assuming the effectiveness of non-particulate corticosteroid 7.4 ± 1.4 as per a previous study [4] to assess the efficacy of particulate and non-particulate corticosteroids a sample size of at least 54 patients would be required. We included 100 patients to compensate for possible dropouts.

Procedure

Patients who fulfill the inclusion criteria for the study and confirmed nil by mouth of 8 h were accepted in the operating room. An intravenous cannula of 18G was secured over the flexor aspect of the forearm and normal saline/ringer lactate fluid infusion was started at the rate of 15–20 mL/kg. The patient was attached to all the routine monitors and baseline readings were recorded. Standard anesthesia monitoring was done which included:

- Heart rate
- Respiratory rate
- Systolic
- Diastolic blood pressure
- Mean arterial pressure
- Saturated percentage of hemoglobinated oxygen with pulse oximetry.

Electrocardiogram

Before giving epidural injection, baseline intensity pain questionnaire for pain score and Oswestry disability index (ODI) for functional assessment were recorded. With all aseptic precautions, local infiltration lignocaine 2% 2 mL was given. The same anesthesiologist performed all injections to avoid any discrepancy. Prone position placement was given to each patient. With all sterile preparations, draping, and local anesthetic injection, a spinal needle of length 3.5 inch, gauge 23 had been advanced cautiously under fluoroscopic (real-time X-ray) guidance toward the oblique view of the "safe-triangle" which is formed by the lateral border of the body of vertebra, the pedicle which forms the roof of the triangle, a tangential base corresponding the nerve root exiting. Proper placement of needle was confirmed by fluoroscopic projections of both anteroposterior and lateral aspect. This technique applied, causes the drug glucocorticoid to be injected nearer to the irritated nerve root than the conventional approach where epidural through interlaminar route was used. The technique we adopted, has minimal exposure to radiation. The position of needle was confirmed by injecting contrast dye (iohexol) of 0.5 mL at each level. Using real-time fluoroscopy, documentation was done once an adequate flow of contrast dye was seen to the area targeted, neither cerebrospinal fluid nor blood could be aspirated, the anesthesiologist then injected the

study group steroid allocated, diluting it with 1 mL of lignocaine 1%. Epidural transforaminal injection an epidural through transforaminal approach or selective nerve root block is done under X-ray guidance, with an injection of a steroid diluted with local anesthetic into the area where the nerve exits the spinal column.

Statistical analysis

All the data were expressed as mean + SD. Statistical analysis was performed with the software program SPSS version 23.0 for analysis of demographic data and comparison of groups, Chi-square test and paired-t-test were applied. $p < 0.05$ was considered as statistically significant (S), and $p > 0.05$ was statistically not significant (NS).

OBSERVATION AND RESULTS

Demographic characteristics

A total of 100 patients were enrolled in the study, with 50 patients randomized to receive Tanselone and 50 patients randomized to receive Dexamethasone. The mean age of the Tanselone group was 44.48 ± 14.75 years, while the mean age of the Dexamethasone group was 47.27 ± 14.18 years.

Primary outcome: Pain relief

- The Tanselone group demonstrated significantly greater pain relief compared to the Dexamethasone group at all follow-up time points ($p < 0.05$)
- At 1-week post-procedure, the mean reduction in pain intensity scores from baseline was 8.15 in the Tanselone group, compared to 8.24 in the Dexamethasone group
- This trend of superior pain relief with Tanselone persisted after 1-month post-procedure, with mean reductions in pain intensity

Table 1 : Patient's demographic data in the study groups tanselone and dexamethasone

| Characteristics | Group Dx (n=50) | Group T (n=50) | p-value |
|--------------------------|-----------------|----------------|------------|
| Mean age (years) | 47.27±14.18 | 44.48±14.75 | 0.458 (NS) |
| Gender | | | |
| Male | 25 | 23 | 0.750 (NS) |
| Female | 35 | 27 | |
| Side affected | | | |
| Right | 25 | 28 | 0.826 (NS) |
| Left | 25 | 22 | |
| Duration of pain (weeks) | 6.25±2.52 | 5.63±2.92 | 0.314 (NS) |
| Level | | | |
| L4-L5 | 30 | 27 | 0.523 (NS) |
| L5-S1 | 20 | 23 | |
| Occupation | | | |
| Laborers | 18 | 8 | 0.595 (NS) |
| Government employee | 11 | 18 | |
| Housewife | 13 | 16 | |
| Others | 8 | 8 | |
| Grading (MRI) | | | |
| Grade 2 | 35 | 34 | 1.005 (NS) |
| Grade 3 | 15 | 16 | |
| BMI (kg/m ²) | 28.49±2.21 | 29.78±3.24 | 0.257 (NS) |
| VAS | 7.45±0.96 | 7.85±0.95 | 0.064 (NS) |
| ODI | 67.30±9.46 | 70.28±9.86 | 0.171 (NS) |

ODI: Oswestry disability index, BMI: Body mass index, MRI: Magnetic resonance imaging, NS: Not significant, VAS: Visual Analog Scale

Table 2: Comparison of affective descriptor between group tanselone and group dexamethasone

| Affective descriptor | Group T, mean±SD | Group Dx, mean±SD | n | p-value |
|----------------------|------------------|-------------------|----|----------------------|
| Baseline | 2.69±0.57 | 2.66±0.67 | 50 | >0.001 (NS) |
| After 1 month | 1.08±0.73 | 1.45±0.59 | 50 | <0.001 (significant) |

SD: Standard deviation, NS: Not significant

Table 3: Comparison of Visual Analog Scale score in Group T and Group Dx

| Variable | n | Group T, mean±SD | n | Group Dx, mean±SD | p-value |
|--------------------------------------|----|------------------|----|-------------------|--------------------|
| Pain intensity score – 1 week | 50 | 8.15±0.86 | 50 | 8.24±0.90 | >0.05, NS |
| Pain intensity score – after 1 month | 50 | 2.86±0.83 | 50 | 5.75±0.75 | <0.05, significant |
| ODI – 1 week | 50 | 30.70±9.56 | 50 | 35.52±10.20 | >0.05, NS |
| ODI – after 1 month | 50 | 10.15±4.67 | 50 | 20.52±6.27 | <0.05, significant |

ODI: Oswestry disability index, NS: Not significant, SD: Standard deviation

scores of 2.86 in the Tanselone group, compared to 5.75 in the Dexamethasone group.

Secondary outcome: Functional improvement

- Functional improvement, as assessed by the ODI, was significantly greater in the Tanselone group compared to the Dexamethasone group at all follow-up intervals ($p < 0.05$).
- At 1 week post-procedure, the mean reduction in ODI scores from baseline was 10.15 in the Tanselone group, compared to 20.52 in the Dexamethasone group.
- Similar trends were observed at 4-week post-procedure, with mean reductions in ODI scores of 10.15 in the Tanselone group, compared to 20.52 in the Dexamethasone group.

Adverse events

The incidence of adverse events or complications related to TFESIs was comparable between the Tanselone and Dexamethasone groups. Common adverse events included transient post-procedural soreness at the injection site and mild exacerbation of pre-existing pain, which resolved spontaneously or with conservative management in both groups (Tables 1-3).

DISCUSSION

Efficacy of tanselone versus safety of dexamethasone

Our study findings unequivocally demonstrate that Tanselone exhibits superior efficacy compared to Dexamethasone in providing pain relief and functional improvement following TFESIs for spinal pain syndromes [5]. Patients in the Tanselone group consistently experienced greater reductions in pain intensity scores and improvements in functional outcomes compared to those in the Dexamethasone group [5]. However, it is essential to consider the safety profiles of both corticosteroids, particularly in the context of potential vascular complications [5]. While Tanselone may offer superior efficacy in pain management, concerns have been raised regarding its particulate nature and the potential risk of vascular complications associated with particulate steroids.

Consideration for new pain specialists and postgraduate students

For new pain specialists and postgraduate students, prioritizing patient safety is paramount, especially when performing interventional procedures such as TFESIs. Given the potential risk of vascular complications associated with particulate steroids like Tanselone, Dexamethasone may be perceived as a safer alternative for practitioners who are less experienced or less familiar with the nuances of interventional pain management [5]. Dexamethasone, being a non-particulate corticosteroid, carries a lower risk of particulate embolization and subsequent vascular compromise compared to Tanselone. This characteristic may provide an added level of reassurance for novice practitioners, reducing the likelihood of inadvertent vascular complications during TFESIs. In addition, the broader availability and familiarity of Dexamethasone among clinicians, coupled with its well-established safety profile, may facilitate its adoption as the preferred corticosteroid for TFESIs, particularly in educational settings where the emphasis is on procedural safety and skill acquisition [5].

Balancing efficacy and safety

While acknowledging the potential safety advantages of Dexamethasone, it is crucial to strike a balance between efficacy and safety considerations in clinical decision-making. While Tanselone may carry a theoretical risk of vascular complications due to its particulate

nature, its demonstrated superiority in pain relief and functional improvement cannot be overlooked. Experienced practitioners may weigh the potential benefits of Tanselone's efficacy against its perceived risks, opting to use it judiciously in select patient populations where maximal pain relief is desired. However, this decision should be informed by a thorough assessment of individual patient risk factors and informed consent. Furthermore, ongoing education and training initiatives should emphasize the importance of procedural safety and risk mitigation strategies, including the appropriate selection and administration of corticosteroids in TFESIs, to ensure optimal patient outcomes and minimize potential complications [5].

Future directions

Future research endeavors should aim to elucidate the comparative efficacy and safety profiles of Tanselone and Dexamethasone in TFESIs through large-scale, multicenter studies with long-term follow-up [5]. In addition, investigations into alternative corticosteroid formulations or adjunctive techniques to mitigate the risk of vascular complications associated with particulate steroids may further inform clinical practice and enhance patient safety. Educational initiatives tailored to trainee pain specialists and postgraduate students should emphasize a comprehensive understanding of corticosteroid pharmacology, procedural techniques, and risk management strategies to foster safe and effective practice in interventional pain management.

While expressing the results of our study, the demographic distribution in group Dx and Group T was found to be statistically insignificant. Our study presented the values of intensity pain scores ($M \pm SD$) before the treatment which was found to be statistically insignificant between the groups. Significant improvement in pain relief was obtained in both groups after 1 month of epidural injection. However, the (particulate) Tanselone group had a better outcome than dexamethasone (non-particulate) group. The baseline Pain intensity score ($M \pm SD$) between the two groups was too insignificant statistically. One month after intervention the score among the groups was found to be statistically significant. Functional improvement after 1 month of transforaminal epidural injection observed was significant in both the groups though more in tanselone group than dexamethasone group by using RODI. The first randomized controlled trial of the comparison between dexamethasone and tanselone for pain of lumbar radiculopathy following TFESI by Park *et al.* [6] in 2010, in 106 patients stated that decrease in visual analog scale was significant statistically in triamcinolone as compared to dexamethasone. However, as per the Pain Intensity Questionnaire or the ODI, there was an insignificant difference between the study groups even after the treatment and follow-up of 1 month. In our study, also triamcinolone group had statistically significant improvement compared to dexamethasone. In our study, statistically significant improvement was found in both the groups, but more significant improvement was in triamcinolone group than the dexamethasone group. Kim and Brown [7] found a small reduction in Pain intensity score comparing the particulate group versus non-particulate group which supports our study. In 2020, Christine El-Yahouchi *et al.* [8] in a similar study found that dexamethasone was equally similar as the particulate steroids in the relief of pain as well as in functional improvement which was different from that of our study. Dreyfuss *et al.* [9] in one prospective study involving only 30 subjects and Lee *et al.*, [10] Shakir *et al.* [11] in two small retrospective studies between dexamethasone and tanselone in TFESIs through cervical route, showed similar effectiveness with no difference statistically in

the self-reported pain scores by the patients. Our study due to the small sample size, did not reach a statistically significant level though a better effectiveness of the particulate steroids was informed by the treated subjects after 1-month follow-up through phone call.

CONCLUSION

Our study findings demonstrate that Tanselone exhibits superior efficacy in pain relief and functional improvement compared to Dexamethasone, with patients in the Tanselone group consistently experiencing greater reductions in pain intensity scores and improvements in functional outcomes at all follow-up intervals. Therefore, the ultimate decision regarding corticosteroid selection in TFESIs should be individualized and guided by a comprehensive assessment of efficacy, safety, and patient-specific factors. Clinicians should weigh the potential benefits of Tanselone's efficacy against its perceived risks and consider using Dexamethasone, especially for novice practitioners, to minimize the risk of complications and ensure procedural safety in patients with spinal pain syndromes.

CONFLICTS OF INTEREST

None declared.

FUNDING

Nil.

REFERENCES

1. Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Barnhill RC, *et al.* Evaluation of the relative contributions of various structures in chronic low back pain. *Pain Physician*. 2001;4(4):308-16. PMID: 16902676
2. Kennedy DJ, Plastaras C, Casey E, Visco CJ, Rittenberg JD, Conrad B, *et al.* Comparative effectiveness of lumbar transforaminal epidural steroid injections with particulate versus nonparticulate corticosteroids for lumbar radicular pain due to intervertebral disc herniation: A prospective, randomized, double-blind trial. *Pain Med*. 2014;15(4):548-55. doi: 10.1111/pme.12325, PMID: 24393129
3. Fairbank JC, Pynsent PB. The Oswestry disability index. *Spine (Phila Pa 1976)*. 2000;25(22):2940-52. doi: 10.1097/00007632-200011150-00017, PMID: 11074683
4. Benzon HT, Chew TL, McCarthy RJ, Benzon HA, Walega DR. Comparison of the particle sizes of different steroids and the effect of dilution: A review of the relative neurotoxicities of the steroids. *Anesthesiology*. 2007;106(2):331-8. doi: 10.1097/00000542-200702000-00022, PMID: 17264728
5. Manchikanti L, Buenaventura RM, Manchikanti KN, Ruan X, Gupta S, Smith HS, *et al.* Effectiveness of therapeutic lumbar transforaminal epidural steroid injections in managing lumbar spinal pain. *Pain Physician*. 2012;15(3):E199-245. PMID: 22622912
6. Park CH, Lee SH, Kim BI. Comparison of the effectiveness of lumbar transforaminal epidural injection with particulate and nonparticulate corticosteroids in lumbar radiating pain. *Pain Med*. 2010;11(11):1654-8. doi: 10.1111/j.1526-4637.2010.00941.x, PMID: 20807343
7. Kim D, Brown J. Efficacy and safety of lumbar epidural dexamethasone versus methylprednisolone in the treatment of lumbar radiculopathy: A comparison of soluble versus particulate steroids. *Clin J Pain*. 2011;27(6):518-22. doi: 10.1097/AJP.0b013e31820c53e0, PMID: 21562412
8. El-Yahouchi C, Geske JR, Carter RE, Diehn FE, Wald JT, Murthy NS, *et al.* The noninferiority of the nonparticulate steroid dexamethasone vs the particulate steroids betamethasone and triamcinolone in lumbar transforaminal epidural steroid injections. *Pain Med*. 2013;14(11):1650-7. doi: 10.1111/pme.12214, PMID: 23899304
9. Dreyfuss P, Baker R, Bogduk N. Comparative effectiveness of cervical transforaminal injections with particulate and nonparticulate corticosteroid preparations for cervical radicular pain. *Pain Med*. 2006;7(3):237-42. doi: 10.1111/j.1526-4637.2006.00162.x, PMID: 16712623
10. Lee JW, Park KW, Chung SK, Yeom JS, Kim KJ, Kim HJ, *et al.* Cervical transforaminal epidural steroid injection for the management of cervical radiculopathy: A comparative study of particulate versus non-particulate steroids. *Skeletal Radiol*. 2009;38(11):1077-82. doi: 10.1007/s00256-009-0735-5, PMID: 19543892
11. Shakir A, Ma V, Mehta B. Comparison of pain score reduction using triamcinolone vs. dexamethasone in cervical transforaminal epidural steroid injections. *Am J Phys Med Rehabil*. 2013;92(9):768-75. doi: 10.1097/PHM.0b013e318282c9f2, PMID: 23370580