Multimodal cocktail analgesic injection in PIVD with lower limb radiculopathy – A mixed design cohort study

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Title -“Multimodal Cocktail Analgesic Injection in PIVD with lower limb radiculopathy – A mixed design cohart study."

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“Multimodal Cocktail Analgesic Injection in PIVD with lower limb radiculopathy – A mixed design cohort study.

Abstract:

**Background:** The role of Sodium Channel Blocker and steroid is well established for pain relief in neuropathic pain by reduce inflammation and desensitization of nerve roots. Our study aims in analyzing the effectiveness of multimodal cocktail injections for radicular pain relief & functional outcome in a patient of intervertebral disc herniation.

**Material and method:** This was an Mixed design (prospective & retrospective) cohort study; included 113 patients between the age group of 18 to 70 years, diagnosed with Prolapse of intervertebral disc (PIVD) with lower limb radiculopathy with MRI finding L4-L5 / L5-S1 vertebral disc involvement. Patients were injected with total 15 ml of cocktail injection in 3 divided doses at 3 identified sites in affected lower limb. Patient was examined & evaluated clinically for VAS pain score, SLRT, Sensory, Motor Examination on day 2, day 7, day 15 & after 1 month.

**Result:** We found that the mean pre-VAS score was 7.83 followed by the mean VAS score post 2 days was 1.05, post 7 days was 3.47, post 15 days was 3.9 and post 30 days was 3.81. There was a statistically significant difference in the mean VAS score (p-value<0.0001). After one month majority of patients (54.62%) had comfortable painless walk and comfortable walking distance increased up to 1km in 45.37% of them.

**Conclusion:** Use of cocktail multimodal injections for radiculopathy pain suggests that this non-operative, OPD based technique could be reasonable, efficient, and safe.
Keywords: radiculopathy, vas score, PIVD, sciatica, sodium channel blockers

INTRODUCTION

Epidural injection (Lignocaine 3% + Triamcinolone 40mg) accelerates pain relief in patients who eventually have natural resolution of radicular pain in a gradual delayed fashion\(^1\). The injection may give relief of pain of variable duration and confirms origin of pain, by relieving it. But Epidural injections are also associated with some adverse events & complications. Complications of Epidural SNRB are due to contaminated epidural steroid injections (mainly due to aspergilosis) resulting in meningitis, stroke, paralysis, and death. Other complications are also being reported with epidural SNRB as life-threatening infections, spinal fluid leaks (0.4-6%), positional headaches (28%), adhesive arachnoiditis (6-16%), hydrocephalus, air embolism, urinary retention, allergic reactions, intravascular injections (7.9-11.6%), stroke, blindness, neurological deficits/paralysis, hematomas, seizures, and death.\(^2\)

Still there is current need of some other safe method of conservative management of PIVD radiculopathy. In different studies pain pathway is little bit different in PIVD radiculopathy as Primary afferent fibers of this pain have a unique morphology, called pseudo-unipolar, wherein both central and peripheral terminals have common axonal stalk. This distinguishes the primary afferent neuron from the typical neuron, where the recipient branch of the neuron (the dendrite) is biochemically distinct from the transmission branch (the axon). The biochemical functional similarity of central and peripheral terminals means that the nociceptor can send and receive messages from either end. This is a very significant functional characteristic.\(^3\)
There is study to see effect of sodium channel blocker on sciatic pain and mechanosensitization of the nerve when injected at distal most part of the nerve. In that study there is good pain relief found with distal injection at the site of tender area found in limb at particular anatomical sites of distal nerves in symptomatic PIVD patients of sciatica. As we found that the role of Sodium Channel Blocker and steroid is well established for pain relief in patients of PIVD to reduce inflammation and desensitization of nerve roots.

In this study we will be analyzing the effectiveness of these multimodal cocktail injections for pain relief & functional outcome of patients.

**Material and method**

This was an Mixed design (prospective & retrospective) cohort study conducted during September 2020 to December 2021 at Department of Orthopaedics & Traumatology, Dr S. N. medical college & attached hospitals, Jodhpur, Rajasthan. The study included all the patients between the age group of 18 to 70 years, attending opd with back pain with lower limb radiculopathy of duration upto 6 months, their MRI showing involvement of L4-L5 / L5-S1 inter-vertebral disc prolapse, lumbar canal stenosis, ligamentum flavum hypertrophy with VAS score more than 5 and also who had undertaken conservative management in form of NSAID/Gabapantoids/opiods/steroids etc. Patients having listhesis, osteoporotic vertebral body fracture, tubercular and pyogenic infection, known hypersensitivity history to Drug used in cocktail Injection and those who have Cardiac Arrhythmia, were excluded. Informed consent was obtained from all participants and institutional review board approval was obtained before initiating the study.
All the patients were assessed for standard neurological examination which included duration of symptoms, walking pattern, comfortable walking distance, SLRT, VAS score, sensory and motor examination. Area of pain was marked to see if it fell in specific dermatome. If symptoms were present in bilateral lower limb then injection was given in more affected side. VAS for pain was marked as numeric and compared in follow up.

Three main specific injection sites were marked anatomically in affected lower limb as shown in figure 1-3.

1. **Deep peroneal nerve near origin:** 1.5 cm antero medial to anterior border of head of fibula or Inferio-Medial angle of a triangle made between Gerdy tubercle of tibia & Centre of head of fibula.

2. **Tibial nerve:** 5 cm just distal to popletial crease in midline between medial & lateral Gastronemius muscle head.

3. **Sural Nerve:** A midpoint between posterior inferior border of lateral malleoli and lateral border of Tendo Achillis.

   All these points were anatomically easy and were confirmed from anatomical books to be commonest part where these nerves will lay. (see anatomical diagrams)

Patients were injected with total 15 ml of cocktail injection in 3 divided doses at 3 identified sites of mentioned composition and dilution. The Needle will be pierced perpendicular to skin while giving injection & drug will be injected as deep as possible.

**Composition detail:**
<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inj. Lignocaine 2% (without Adrenaline &amp; without preservatives)</td>
<td>4.5 ml</td>
</tr>
<tr>
<td>Inj. Triamcinolone</td>
<td>80 mg (2ml)</td>
</tr>
<tr>
<td>Inj. Clonidine</td>
<td>150 µg (1ml)</td>
</tr>
<tr>
<td>Distilled Water</td>
<td>7.5 ml</td>
</tr>
<tr>
<td>Total dose</td>
<td>15 ml</td>
</tr>
</tbody>
</table>

After injection patient was kept under observation for 30 minutes in OPD. After 30 minutes patient was evaluated, if any adverse event found patient was managed accordingly.

In further follow up there was no neuropathic or analgesic drug given after injection and patients were evaluated clinically for VAS pain score, SLRT, Sensory, Motor Examination & for any adverse event on day 2, day 7, day 15 & after 1 month.
Results

In this study we analysed 113 patients in OPD at Department of Orthopaedic, Dr S. N. medical college & attached hospitals. 5 patients had lost the followup. The mean age of patients is 42.43 years. There was 55% males with mean age is 40.06 years and 45% females with mean age is 45.29 years.

In our study majority of patients (51%) had injection on left side followed by 49% had injection on right side. Seven (6.19%) patients had shown no improvement in pain vas score ,comfortable walking distance after one week of post injection . They were labeled as a failed block, and repeat cocktail injection was given on day 7,after they all were responded .

Complain of all patients had complication of Dryness of mouth up to 24 hours followed by 4% had Dizziness within 30 minutes and 90% had Abnormal tingling sensation up to 24 hours. 30% had local injection site bruise or ecchymosis which resolved spontaneously in three to five days. Out of 113 patients ,fifteen (13.27 %) patients had diabetes or HTN or both, out of those fifteen patients Only one patient with uncontrolled diabetes developed cellulitis of leg ,which was managed with su-mag dressing and oral antibiotics.

The mean pre-VAS score was 7.83 followed by mean VAS score post 2 days was 1.05, post 7 days was 3.47, post 15 days was 3.9 and post 30 days was 3.81. There was statistically significant difference in mean VAS score (p-value<0.0001) as shown in table-1.

Here, 13.90% patients came to us on wheel chair followed by 45.40% use support for walking and 40.74% had painful walking before start of treatment . But after 1 month only 1.85% were
on wheel chair, 16.70% use support for walk, 26.85% had painful walk, majority (54.62%) had comfortable painless walk as shown in table-2.

Initially, 41.51% patients had comfortable walk up to 10 meters, 24.53% had walk up to 100 meters, 18.87% had walk up to 1 kilometres and 15% had no comfortable walk. But after 1 month of injection only 2 patients had no comfortable walk followed by 8.33% walk for only 10 meters, 37.80% walk for 100 meters and 45.37% patients walk for 1km as shown in table-3.

Discussion

In most cases of low back pain, radicular pain is easily diagnosed in clinical practice⁴. The primary pathophysiological mechanism for inducing radiculopathy was thought to be mechanical compression of a nerve root by a protruding disc, but new experimental studies⁵ demonstrates that nerve inflammation is yet another, and possibly the more crucial pathophysiological mechanism for stimulating lumbar radiculopathy⁶.

For the vast majority of patients, non-operative management of radicular pain is the preferred therapeutic option. A multimodal approach to non-operative care should include anti-inflammatory drugs, education, and physical therapy⁷.

Injecting a multimodal cocktail is a safe, reliable and cost-effective treatment that may affect in reducing pain and suppressing inflammation. Although the analgesic efficacies of numerous therapeutic combinations for local injection following total knee arthroplasty have been widely
studied, there is no standard approach for drug combinations. This injection combination typically has a multi-component composition based on local anesthetics and epinephrine, as well as other medications such as non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, opioids, and so on.\(^8\)

In our study, we employed a multimodal cocktail injection of Lignocaine 2 % (without Adrenaline and preservatives), Triamcinolone, and Clonidine for alleviating radicular pain as a non-operative treatment.

Allodynia (pain caused by ordinarily non-painful stimuli) and/or hyperalgesia are common symptoms of neuropathic pain. Neuropathic pain can develop as a result of an increase in intrinsic neuronal excitability, which is usually expressed in ectopically produced or minimally stimulated impulses. Changes in sodium channel trafficking, gene expression, and/or channel kinetics due to nerve injury can all contribute to the remodelling of neuronal membranes and hyperexcitability associated with neuropathic pain.\(^9\) As a result, voltage-gated sodium channels are promising targets for the production of new pain medicines. Tricyclic antidepressants (TCAs: amitriptyline and nortriptyline), local anesthetics (lignocaine, mexiletine) are currently used medications for the treatment of neuropathic pain that have proven actions against sodium channels.\(^10\)

Triamcinolone, a corticosteroid had been used to eliminate inflammation. According to previous research studies, corticosteroid injections may provide short-term relief from leg discomfort and sensory impairments, but they may not lessen the need for surgery or provide significant functional benefit.\(^11\) Infliximab, a TNF inhibitor, was reported to be beneficial in the treatment of sciatica in patients with radicular pain by Korhonen et al.\(^12\) They found that 1-year response
significantly improved with 3mg/kg infliximab over periradicular saline in leg pain (P = 0.005) and disability (P = 0.003). Neurologic abnormalities normalized more comprehensively in the infliximab group (P = 0.001). But The results of this randomized trial do not support the use of infliximab for lumbar radicular pain in patients with disc herniation-induced sciatica. Freeman et al.\textsuperscript{13} demonstrated a significant reduction in both worst leg pain (WLP) and worst back pain (WBP) scores. They examine the safety and efficacy of three different doses of the tumor necrosis factor alpha (TNF-\(\alpha\)) inhibitor etanercept versus placebo for the treatment of symptomatic lumbar disc herniation. Patients receiving 0.5-mg etanercept showed a clinically and statistically significant (P< 0.1) reduction in mean daily WLP compared with the placebo cohort from 2 to 26 weeks for both the per protocol population (-5.13 vs. -1.95; P= 0.066) and the intention-to-treat population (-4.40 vs. -1.84; P= 0.058). Fifty percent of these subjects reported a 100% reduction in WLP 4 weeks post-treatment compared with 0% of subjects in the placebo cohort. In our study, mean pre-VAS score was 7.83, which was significantly improved (3.81) at the end of one month with p-value <0.0001, but there was no improvement in axial backache.

The mechanism of action of clonidine in the CNS for pain management is that many pain signals originate in the dorsal horn of the spinal cord and are transmitted to higher CNS centres. The descending inhibitory bulbospinal neurons release norepinephrine, which binds to alpha-2-receptors in the dorsal horn to reduce afferent pain transmission and generate analgesia. As a result, medications that target alpha-2 receptors, such as clonidine, can significantly affect pain transmission\textsuperscript{14}. B K Bral \textsuperscript{15} et al assess the effectiveness of epidural steroid injection for low back and radicular pain. They found that the functional status and pain response was improved in 81% of the patients during all the follow-up periods (p < 0.001). Lignocaine injection was
delivered by Gore et al to all pain points (50 at sinus tarsi for lateral terminal deep peroneal nerve (LTDPN), 30 at the lateral wall for sural nerve pain) by. At 10 minutes postinjection, relief of pain is noted. Average VAS scores decreased from 7 preinjection to 1 for patients in the LTDPN group; for patients in the sural nerve treatment group, average VAS scores decreased from 8 to 2. At 30 minutes posttreatment, no patients in the LTDPN group reported any pain; only 3 of the 24 patients in the sural nerve treatment group reported a VAS greater than 0 (1 in all cases) and duration of relief averaged 8 hours (range 3-36 hours). In a Case series which was published in 1960, where distal to lesion block was studied to relieve pain from a large area supplied by the nerve by blocking the afferent from that area. “Evidence that local anesthetic injections of the afferent pathway, distal to the site of the lesion, may stop the pain or paraesthesia that may far outlast the duration of the anesthesia; and blocking a peripheral nerve supplying a large part but not the whole of the region where the pain or paraesthesia are felt may remove these sensations from the entire region.17 Another study by Xavier et al highlights peripheral inputs as a cause of pain during distal block study. 18,19 The effectiveness of common peroneal nerve block for lumbar disc herniation was evaluated in a double blind study by Tajiri et al.20 Common peroneal nerve block was performed near the fibular head in nine patients using 2% lidocaine and in 10 patients using saline. The average pain scale score decreased from 3.1 to 0.6 in the lidocaine group, whereas it decreased from 3.0 to 2.6 in the placebo group. The average result in the straight leg raising test increased from 61 degrees to 84 degrees in the lidocaine group, but from 44 degrees to 50 degrees in the placebo group. Lower leg pain lessened more in the lidocaine group than in the placebo group. Selective Nerve Root Block (SNRB), injected with a combination of 40 mg of Methylprednisolone based suspension with local anaesthetic over the affected nerve root to 40 patients with various grades of disc prolapse
affecting a particular lumbar nerve root presenting with chronic radicular pain were identified irrespective of age and sex. All were and results were analyzed. Those graded mild had 4.3 months relief and those graded moderate had 2.5 months relief. Those with severe disc prolapse had no relief except for the immediate postprocedural relief. Only 20% patients had relief up to 6 months. Ninja et al reported a case of 50 year old woman who was presented with neuropathic pain in the left lower limb after resection of a schwannoma on the left S1 nerve root, 20 mL of the anesthetic mixture were injected. The patient had immediate pain relief after the block (VAS 1/10). She remained pain free for 15 days after which pain reappeared but with less severity (3/10). Repetitive sciatic nerve block was performed in a progressive manner and was shown to be effective in managing neuropathic pain.

In this study, we investigated the efficacy of multimodal cocktail injections for pain management and patient functional outcomes as a conservative treatment option.

The mean age of patients was 42.43 years. There were 54.72% males with mean age of 40.06 years and 45.28% females with a mean age of 45.29 years. Majority of the patients (50.94%) had an injection on the left side followed by 49.06% , injection on the right side.

We found that , mean pre-VAS score was 7.83 followed by, the mean VAS score after 2 days was 1.05, after 7 days was 3.47, after 15 days was 3.9 and after 1 month was 3.81. There was a statistically significant difference in the mean VAS score (p-value<0.0001).

At the time of presentation, 13.90 % of patients were wheelchair bound , 45.40 % needed walking assistance, and 40.74 % had difficulty in walking. However, after one month, only 1.85 % was wheelchair bound, 16.70 % needed assistance to walk, 26.85 % had a painful walk, and
the majority (47.22%) had a pain-free walk. At the time of presentation, 41.70% of patients were able to walk comfortably for 10 meters, 25.92% for 100 meters, 18.52% for 1 km, and 13.90% had no comfortable walk. After cocktail injection, Only two patient had no comfortable walk after one month, followed by 8.33% who could only walk 10 meters, 37.80% who could walk 100 meters, and 45.37% who could walk up to 1 km without pain. Manchikanti et al.4 conducted a study that was similar to this study. They evaluated the efficacy of caudal epidural injections with or without steroids in treating chronic low back and lower extremity pain caused by disc herniation or radiculitis, as well as the differences between local anesthetics with and without steroids in providing efficient and long-lasting pain relief. At the end of a year's follow-up, their study found significant pain relief (50%) in 79% to 81% of patients, as well as significant improvement in functional status (40% or greater reduction in Oswestry scores) in 83 to 91% of patients, with no major differences noted with or without steroids. Opioid consumption and employment both improved significantly. Both groups had significant reductions in opioid intake, as well as pain alleviation and improved functional status. Furthermore, when compared to baseline employment, Group II saw a considerable increase in employment.

In a randomized trial of 84 patients with lumbosacral radiculopathy of less than 6 months duration, Cohen et al23 reported that Subjects who received 2 epidural injections of corticosteroids, etanercept (4 mg) or saline, mixed with bupivicaine. A greater reduction in leg pain 1 month after the second injection was observed with corticosteroids than etanercept or saline. Despite its extensive use and numerous publications, there is much debate on the medical necessity and criteria for lumbar epidural injections4. In positive reports for treating radicular
pain from herniated lumbar intervertebral discs and radiculitis, multiple systematic reviews, guidelines and other evaluations have revealed indications for caudal epidural injections.

In the past, study shown serious systemic complications of epidural corticosteroid \(^2\) but here we discovered that patients had a mild complication like Dryness of mouth for up to 24 hours in all, 3.77 \% had a complication of Dizziness within 30 minutes, and 84.91 \% had a condition of Abnormal tingling sensation for up to 24 hours, no serious systemic side effect was noted.

Patients undergoing discectomy for lumbar disc herniation often report a prompt reduction in leg pain, but many complain of persistent or in some cases worse low back pain after surgery.\(^{24}\) Moreover, long-term outcomes of conservative management have been reported to be better than surgical intervention in several studies \(^{25-26}\). Additionally, surgical intervention is not available for everyone who is symptomatic and may lead to failure in approximately 25\% of carefully selected cases \(^{27}\).

Hence we tried to resort to an alternative method of treatment that entailed only non-operative treatment of the prolapse intervertebral disc based on this concept of multimodal cocktail injection. We discovered that injecting a mixture of multimodal injections into the affected spinal segments without attempting to "decompress" the bones, soft tissues, or disc is an effective nonsurgical therapeutic strategy. However axial backache was not improved but leg pain ,comfortable walking distance improved significantly.

LIMITATION - In this study, patient were assessed for short period of time , long term follow-up will require for further evaluation.

CONCLUSION
Although the direct surgical excision of the herniated disc material is widely acknowledged for the treatment of PIVD, the use of cocktail multimodal injections for radiculopathy pain suggests that this non-operative, OPD based technique could be reasonable, efficient, and safe.

References


prolonged pain control and better recovery following total knee arthroplasty?: study protocol for a randomized controlled trial. Trials. 2021 Oct 15;22(1):703.


17. Relief of pain and paraesthesiae by nerve block distal to a lesion. KIBLER RF, NATHAN PW. J Neurol Neurosurg Psychiatry. 1960 May;23:91-8.


Institutional Ethics Committee  
Dr. Sampurnanand Medical College, Jodhpur  
ETHICAL CLEARANCE CERTIFICATE

No. SNMC /IEC/2020/ 1158-1160  
Date: 18.12.2020

Certificate Reference Number: SNMC /IEC/2020/Plan /347

Project title- "A MIXED DESIGN COHORT STUDY TO MEASURE THE EFFECTIVENESS OF MULTIMODAL COCKTAIL ANALGESIC INJECTION IN DISTAL LOWER LIMB FOR MANAGEMENT OF PIVD RADICULOPATHIC PAIN & FUNCTIONAL OUTCOME IN PATIENTS HAVING PAIN VAS SCORE MORE THAN 5 WITH CONSERVATIVE MANAGEMENT."

Nature of Project : Thesis plan
Principal Investigator: Dr Bharat Bhushan  
(PG Student)  
(Deptt. of Orthopaedic )  
(Through Guide)

Guide/ Supervisor: Dr Arun Vaishy

This is to inform that members of institutional Ethics Committee, under the Chairmanship of Dr. Inder Dev Arya (Group Coordinator Research, AFRI & Scientist-"G") and after through consideration accorded it’s approval on above plan. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

If your above project is involved in clinical / drug trial, you are required to submit fee of Rs. 15,000/- for your above research project in form of Demand Draft in favor of ”Secretary, Rajasthan Medicare Relief Society, Jodhpur”, immediately to this office as per rules of the State Government.

Dr. SNMC IEC shall have an access to any information or data at any time during the course or after completion of the plan/proposal. On behalf of Ethics Committee, I wish you success in your research.

Dr. Anusuya Gehlot  
Member secretary  
Institutional Ethics Committee  
Dr. SNMC, Jodhpur
Tables-

**Table 1: VAS Score**

<table>
<thead>
<tr>
<th>Follow up</th>
<th>VAS Score</th>
<th>t value</th>
<th>p value</th>
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<tbody>
<tr>
<td></td>
<td>Mean±SD</td>
<td>Mean difference</td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>7.83±0.87</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Post 2 days</td>
<td>1.05±0.63</td>
<td>6.774</td>
<td>52.84</td>
</tr>
<tr>
<td>Post 7 days</td>
<td>3.47±2.79</td>
<td>4.35</td>
<td>12.33</td>
</tr>
<tr>
<td>Post 15 days</td>
<td>3.9±2.70</td>
<td>3.9</td>
<td>10.92</td>
</tr>
<tr>
<td>Post 30 days</td>
<td>3.81±2.66</td>
<td>3.98</td>
<td>11.19</td>
</tr>
</tbody>
</table>

**Table 2: Ambulatory method**

<table>
<thead>
<tr>
<th>Ambulatory method</th>
<th>Pre</th>
<th>after 1 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wheel chair</td>
<td>15 (13.90%)</td>
<td>2 (1.85%)</td>
</tr>
<tr>
<td>Walk with support</td>
<td>49 (45.40%)</td>
<td>18 (16.70%)</td>
</tr>
<tr>
<td>Painful walking</td>
<td>44 (40.74%)</td>
<td>29 (26.85%)</td>
</tr>
<tr>
<td>Comfortable painless walking</td>
<td>0</td>
<td>59 (54.62%)</td>
</tr>
<tr>
<td>Total</td>
<td>108</td>
<td>108</td>
</tr>
</tbody>
</table>
Table 3: Comfortable walking distance

<table>
<thead>
<tr>
<th>Comfortable walking distance approx</th>
<th>Pre</th>
<th>after 1 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 meter</td>
<td>45 (41.70%)</td>
<td>9 (8.33%)</td>
</tr>
<tr>
<td>100 meter</td>
<td>28 (25.92%)</td>
<td>41 (37.80%)</td>
</tr>
<tr>
<td>1 kilometre</td>
<td>20 (18.52%)</td>
<td>49 (45.37%)</td>
</tr>
<tr>
<td>&gt;1 kilometre</td>
<td>0</td>
<td>7 (6.50%)</td>
</tr>
<tr>
<td>Nill</td>
<td>15 (13.90%)</td>
<td>2 (1.85%)</td>
</tr>
<tr>
<td>Total</td>
<td>108</td>
<td>108</td>
</tr>
</tbody>
</table>
FIGURES- Three main specific injection sites were marked anatomically in affected lower limb as shown in figure 1-3.