Background: Cost utility or cost effective analysis continues to take center stage in the United States for defining and measuring the value of treatments in interventional pain management. Appropriate cost utility analysis has been performed for caudal epidural injections, percutaneous adhesiolysis, and spinal cord stimulation. However, the literature pertaining to lumbar interlaminar epidural injections is lacking, specifically in reference to cost utility analysis derived from randomized controlled trials (RCTs) with a pragmatic approach in a practical setting.

Objectives: To assess the cost utility of lumbar interlaminar epidural injections in managing chronic low back and/or lower extremity pain secondary to lumbar disc herniation, spinal stenosis, and axial or discogenic low back pain.

Study Design: Analysis based on 3 previously published randomized trials of effectiveness of lumbar interlaminar epidural injections assessing their role in disc herniation, spinal stenosis, and axial or discogenic pain.

Setting: A contemporary, private, specialty referral interventional pain management center in the United States.

Methods: Cost utility of lumbar interlaminar epidural injections with or without steroids in managing lumbar disc herniation, central spinal stenosis, and discogenic or axial low back pain was conducted with data derived from 3 RCTs that included a 2-year follow-up, with inclusion of 360 patients. The primary outcome was significant improvement defined as at least a 50% in pain reduction and disability status. Direct payment data from 2016 was utilized for assessment of procedural costs. Overall costs, including drug costs, were determined by multiplication of direct procedural payment data by a factor of 1.67 to accommodate for indirect payments respectively for disc herniation, spinal stenosis, and discogenic pain.

Results: The results of 3 RCTs showed direct cost utility for one year of quality-adjusted life year (QALY) of $2,050.87 for disc herniation, $2,112.25 for axial or discogenic pain without disc herniation, and $1,773.28 for spinal stenosis, with an average cost per one year QALY of $1,976.58, with total estimated costs of $3,425, $3,527, $2,961, and $3,301 respectively.

Limitations: The limitation of this cost utility analysis includes that it is a single center evaluation, even though 360 patients were included in this analysis. Further, only the costs of interventional procedures and physician visits were assessed based on the data, with extrapolation of indirect costs presenting the overall total costs. The benefits of returning to work were not assessed.

Conclusion: This cost utility analysis of lumbar interlaminar epidural injections in patients nonresponsive to conservative management in the treatment of disc herniation, central spinal stenosis, and axial or discogenic low back pain in the lumbar spine shows the clinical effectiveness and cost utility of these injections of $1,976.58 for direct costs with a total cost of $3,301 per QALY.
With the passage and implementation of the Affordable Health Care Act (ACA) (1-3), focused on quality (4-10) and reduction in cost of care (1-3,11). Increasing attention has been focused on defining and measuring the value of interventions in general, and interventional techniques in particular (12-38). The increasing prevalence of chronic low back with or without lower extremity pain and health care costs, which have been described as escalating at an unsustainable rate, are continuing problems in managing spinal pain (39-53). In addition to escalating use of surgical interventions (42,43,52,53), various non-surgical interventions are extensively utilized with variable and often discordant conclusions of safety and effectiveness (12,13,46-51,54-74). Among these modalities, lumbar epidural injections are a commonly used modality in disc herniation, discogenic pain, and spinal stenosis prior to surgical intervention, after the failure of surgical intervention, in patients with or without indications or contraindications for surgical intervention (12,13,54-58,63,64,71-78).

Lumbar epidural access with an interlaminar approach is one of the commonly used approaches in managing low back and lower extremity pain apart from caudal epidural injections and transforaminal epidural injections (12,13,54-58,63,64,71-78). Consequently, the use of these procedures has been increasing significantly (46,47,49). The studies of the Medicare population showed that while all interventional techniques for chronic pain increased 153% per 100,000 Medicare beneficiaries from 2000 to 2014 (46,47), overall lumbar epidural injections increased 99%, and lumbar transforaminal epidurals increased 609%, whereas lumbar epidurals including interlaminar and caudal decreased 2% (49).

Martin et al (39), in the assessment of health care expenditures in managing back and neck problems, found that expenditures totaled approximately $86 billion. These expenditures showed that there was an increase of 49% in the number of patients seeking spine-related care while the expenses increased 65%. Gaskin and Richard (45) showed costs of chronic pain of approximately $100 billion per year. More recently, Dieleman et al (40), in evaluating US spending on personal health care and public health from 1996 to 2013, showed that low back and neck pain accounted for the third highest amount, with estimated health care spending of $87.6 billion in 2013. Further, they also showed that spending on low back and neck pain and on diabetes increased the most over the 18 years, by an estimated $57.2 billion and $64.4 billion, respectively.

Due to continued escalating health care costs and debate on the effectiveness of multiple interventions, cost effectiveness or cost utility analysis has become a cornerstone in health policy including for epidural injections (16-28). The cost utility has been described to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived in full health by the patient receiving the intervention. As such, it can be considered as a special type of cost effectiveness analysis. Thus, cost effectiveness and cost utility are sometimes mistakenly used interchangeably. In a scenario of cost utility analysis, cost is measured in monetary units, unlike a cost-benefit analysis in which the benefit does not have to be expressed in monetary terms. Numerous interventions conducted in assessing the cost utility analysis have resulted in highly variable conclusions. Two well publicized cost effectiveness analysis studies of surgical versus nonoperative treatment for lumbar disc herniation and spinal stenosis with and without degenerative spondylolisthesis showed $69,403 per quality-adjusted life year (QALY) in managing lumbar disc herniation, $77,600 in managing spinal stenosis without degenerative spondylolisthesis, and $115,600 in managing spinal stenosis with degenerative spondylolisthesis (23,24). Similarly, Taylor et al (27) showed cost effectiveness of spinal cord stimulation at £5,624 per QALY. Cost utility analysis was performed for interventional techniques utilizing RCTs by Manchikanti et al (25,26) and showed cost utility of caudal epidural injections at $2,172.50 in 480 patients suffering with various conditions and $2,650 in percutaneous adhe-
sis in the United States. However, Manchikanti et al provided the data only on direct procedural costs without inclusion of indirect costs or drug therapy. Tosteson et al (23,24), in their landmark cost utility analysis, showed direct costs of 60% in spinal stenosis, 68% in disc herniation, and 71% in spinal stenosis with degenerative spondylolisthesis, with highest indirect costs for spinal stenosis of 40%. Thus, utilizing direct medical costs at 60%, the data from Manchikanti et al (24-26) was multiplied by 1.67, deriving cost utility of caudal epidural injections of $3,628 per QALY (25) and $4,426 for percutaneous adhesiolysis per QALY (26).

We sought to derive a reliable and valid overall assessment of cost utility data with assessment of direct costs and addition of drug and indirect costs, utilizing 3 lumbar interlaminar epidural injections RCTs in disc herniation, central spinal stenosis, and discogenic pain with low back and lower extremity pain with a 2-year follow-up (76-78).

**Methods**

**Study Design**

The cost utility analysis for this assessment was performed based on 3 double-blind RCTs, which assessed effectiveness of lumbar interlaminar epidural injections in managing low back and lower extremity pain secondary to disc herniation (78), discogenic or axial pain without disc herniation (76), and lumbosacral central spinal stenosis (77). The methodology utilized in performing these studies has been described in their respective manuscripts (76-78). Appropriate diagnosis was established in all patients with disc herniation, axial or discogenic pain, and central spinal stenosis based on a multitude of investigations including diagnostic facet joint nerve blocks in patients with discogenic pain. Further, all the patients have failed conservative management with structured exercise program, physical therapy or occupational therapy, and drug therapy.

**Outcome Measures**

Outcome measures included pain rating and disability status. Pain rating was determined on an 11-point Numeric Rating Scale (NRS) and disability and functional status were assessed based on a 50-point Oswestry Disability Index (ODI). Intermittent post treatment outcomes were assessed for 2 years. Primary outcome was determined as significant improvement of 50% reduction in pain and increase in function.

**Analysis**

Each trial consisted of 120 patients assigned to either a control group receiving 6 mL of 0.5% local anesthetic only or an intervention group receiving 5 mL of 0.5% local anesthetic mixed with 6 mg of 1 mL of Celestone.

Detailed analysis is provided in the manuscripts (76-78). For analysis of the direct procedural cost utility, reimbursement rates were utilized from 2016 for calculating costs for physician services and the facility costs based on each patient’s payer status. Overall costs were estimated by multiplying direct procedural costs by a factor of 1.67 based on previous studies (23,24).

**Results**

**Patient Flow**

Figure 1 shows the patient flow diagram of the RCTs of 3 lumbar interlaminar epidural injection trials.

**Outcomes**

Table 1 shows baseline demographic characteristics of patients enrolled in 3 trials. Table 2 shows characteristics of pain relief and functional status improvement as evaluated by NRS and ODI. Figure 2 shows the proportion of patients with significant reduction in pain scores and improvement in ODI scores.

**Adverse Events**

No additional costs were incurred due to adverse events occurring in any of the 360 patients during the study period.

**Cost Utility Analysis**

Cost utility analysis was based on the quality of life improvement and cost for procedure per QALY based on the primary outcomes of pain relief and improvement in functional status. As shown in Table 3, direct cost utility for one-year improvement in QALY was $2,050.87 for disc herniation, $2,112.25 for discogenic pain, and $1,773.28 for spinal stenosis. Overall direct procedural cost utility for one year of improvement in quality of life was $1,976.58. Average total direct cost per patient in 2 years was $2,496.17. Total costs for one-year improvement of quality of life with multiplication of direct cost by a factor of 1.67 showed cost utility of $3,425 for disc herniation per QALY, $3,527 for discogenic pain per QALY, $2,961 for spinal stenosis per QALY, and $3,301 on average for all epidural injections per QALY.
The cost utility analysis was derived from 3 RCTs with a 2-year follow-up with data from 360 patients, nonresponsive to conservative management, undergoing lumbar interlaminar epidural injections with outcomes data. The results showed overall 74% of the patients met the primary outcome criteria of significant improvement with 50% pain relief and improvement in functional status with 69% at the end of 2 years. The total costs for one-year improvement in QALY were $3,425 for disc herniation, $3,527 for discogenic pain, and $2,961 for central spinal stenosis, with an average of $3,301 for interlaminar epidural treatment with local

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**Table 1.** Baseline demographic characteristics of patients of lumbar interlaminar epidural injections trials of disc herniation, discogenic pain, and spinal stenosis (76-78).

<table>
<thead>
<tr>
<th></th>
<th>Discogenic Pain</th>
<th>Disc Herniation</th>
<th>Spinal Stenosis</th>
<th>Pooled</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>120</td>
<td>120</td>
<td>120</td>
<td>360</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>42 ± 11.6</td>
<td>45 ± 13.9</td>
<td>52* ± 14.6</td>
<td>46 ± 14.1</td>
<td>0.001</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>32% / 68%</td>
<td>50% / 50%</td>
<td>43% / 57%</td>
<td>43% / 57%</td>
<td>0.014</td>
</tr>
<tr>
<td>Duration of Pain (months)</td>
<td>116 ± 99.4</td>
<td>134 ± 114.9</td>
<td>115 ± 92.7</td>
<td>122 ± 102.6</td>
<td>0.227</td>
</tr>
<tr>
<td>Mode of Onset of the Pain (Gradual)</td>
<td>68%</td>
<td>67%</td>
<td>80%*</td>
<td>72%</td>
<td>0.044</td>
</tr>
</tbody>
</table>

**Discussion**

The cost utility analysis was derived from 3 RCTs with a 2-year follow-up with data from 360 patients, nonresponsive to conservative management, undergoing lumbar interlaminar epidural injections with outcomes data. The results showed overall 74% of the patients met the primary outcome criteria of significant improvement with 50% pain relief and improvement in functional status with 69% at the end of 2 years. The total costs for one-year improvement in QALY were $3,425 for disc herniation, $3,527 for discogenic pain, and $2,961 for central spinal stenosis, with an average of $3,301 for interlaminar epidural treatment with local

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**Fig. 1.** Patient flow diagram of randomized controlled trials of lumbar interlaminar epidural injections (76-78).
Cost Utility Analysis of Lumbar Interlaminar Epidural Injections

Table 2. Pain relief and functional status improvement evaluated by Numeric Rating Scale (NRS) and Oswestry Disability Index (ODI) (76-78).

<table>
<thead>
<tr>
<th>Numeric Rating Scores</th>
<th>Disc Herniation</th>
<th>Discogenic Pain</th>
<th>Central Spinal Stenosis</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>8.1 ± 0.9</td>
<td>7.8 ± 0.9</td>
<td>8.0 ± 0.9</td>
<td>8.0 ± 0.9</td>
</tr>
<tr>
<td>6 months</td>
<td>3.8* ± 1.4 (79%)</td>
<td>3.7* ± 1.1 (79%)</td>
<td>3.8* ± 1.7 (78%)</td>
<td>3.8* ± 1.4 (79%)</td>
</tr>
<tr>
<td>12 months</td>
<td>3.7* ± 1.4 (78%)</td>
<td>3.7* ± 1.2 (74%)</td>
<td>3.7* ± 1.8 (75%)</td>
<td>3.7* ± 1.5 (76%)</td>
</tr>
<tr>
<td>24 months</td>
<td>3.9* ± 1.5 (67%)</td>
<td>3.7* ± 1.4 (73%)</td>
<td>3.7* ± 1.8 (73%)</td>
<td>3.8* ± 1.6 (71%)</td>
</tr>
</tbody>
</table>

Oswestry Disability Index Scores

| Baseline              | 30.0 ± 4.8 | 29.9 ± 4.9 | 30.7* ± 7.4 | 30.2* ± 5.8 |
| 6 months              | 14.8* ± 5.7 (76%) | 14.9* ± 5.0 (75%) | 14.9* ± 6.1 (76%) | 14.9* ± 5.6 (76%) |
| 12 months             | 14.4* ± 5.8 (78%) | 15.0* ± 5.7 (73%) | 14.7* ± 6.4 (75%) | 14.7* ± 6.0 (75%) |
| 24 months             | 14.8* ± 6.0 (68%) | 14.7* ± 5.6 (71%) | 14.4* ± 6.9 (75%) | 14.7* ± 6.2 (71%) |

(_____ ) illustrates proportion with significant pain relief (≥ 50%) from baseline

* significant difference with baseline values (P < 0.001)

Fig. 2. Proportion of patients with significant reduction in Numeric Rating Scale (NRS) and Oswestry Disability Index (ODI) scores (≥ 50% reduction from baseline) (76-78).

anesthetics with or without steroids. A lower cost for spinal stenosis of $2,961 compared to $3,527 for discogenic pain appears to show a non-significant difference based on somewhat higher significant improvement per procedure of 13.2 ± 12.7 weeks compared to the average improvement of 11.5 ± 8.8 weeks. Consequently, the number of procedures performed in the spinal stenosis group were also less compared to the disc herniation and discogenic pain groups.

The results of the present assessment are similar to previously published cost utility analysis of caudal epidural injections utilizing similar methodology performed in the same clinical setting with a pragmatic approach at an average cost of $3,628 per QALY (25). However, the cost utility of lumbar interlaminar epidural injections compared to the previous analysis, based on RCTs of percutaneous adhesiolysis, is lower than $4,426 per QALY (26). In addition, the cost utility analysis also shows lower cost compared to spinal cord stimulation in post lumbar surgery syndrome of CAN $9,293 per QALY (30) and £5,624 per QALY (27). These results are also superior to the results by Whynes et al (79) reporting the cost effectiveness of lumbar interlaminar epidural injections at £8,975 per QALY, which was rather more expensive than spinal cord stimulation.

In global analysis of various modalities of interventions utilized in spine treatment in a systematic review, Kepler et al (19) analyzed 33 studies with only 45% of the cost utility assessments showing costs less than $100,000 per QALY, whereas around 23% showed costs greater than $100,000 per QALY. Similarly, Indrakanti et al (20), assessing cost utility analysis of value-based care in 27 studies, showed that studies of nonoperative treatments demonstrated greater value. Dagenais et
al (16) also showed cost utility to range from $304 to $579,527, with a median cost of $13,015 per QALY.

Thus, lumbar interlaminar epidural injections are also superior in terms of quality adjusted life years to non-interventional conservative management treatments. As an example, an exercise program and education were found to be superior to education alone, for patients with low back pain for more than 3 months, resulting in a QALY of $8,650 (80). Fritz et al (38) conducted a cost effectiveness study of primary care management for acute low back pain and showed early physical therapy resulted in better quality of life with an incremental cost effectiveness ratio of $32,058 per QALY. They emphasized the importance of simultaneously conducting clinical effectiveness and cost effectiveness, since for a condition such as low back pain, nearly all interventions are characterized by small treatment effects.

Multiple surgical interventions have been assessed for cost utility and cost effectiveness analysis in conjunction with the clinical effectiveness. Tosteson et al (23,24) assessed the clinical effectiveness data from the SPORT trials for surgical treatment for disc herniation relative to nonoperative care and found cost effectiveness was $69,403 per QALY gained in the general population and $34,355 in the Medicare population. They also showed cost effectiveness in patients with stenosis with decompressive laminectomy was $77,600 per QALY compared to stenosis with degenerative spondylolisthesis, undergoing fusion and instrumentation at a cost of $115,600 per QALY.

This cost analysis is limited to the total cost of medical care given and does not include any monetary benefits that ensued from treatment, including return to work. At baseline, of 112 patients in this analysis, eligible for employment, 75 were employed, with 95 employed at end of 2 years, an increase in employment from 67% to 85%.

NICE -- the National Institute for Health and Clinical Excellence (81) in the United Kingdom is well known for assessment of the cost effectiveness of potential expenditures within the National Health Services. NICE assesses the cost effectiveness of treatments by analyzing the cost and benefit of the proposed treatment relative to the next best treatment. NICE accepts as cost effective those interventions with an incremental cost

Table 3. Cost utility analysis of lumbar interlaminar epidural injections in managing pain and disability of disc herniation, discogenic pain, and spinal stenosis.

<table>
<thead>
<tr>
<th></th>
<th>Disc Herniation</th>
<th>Discogenic Pain</th>
<th>Spinal Stenosis</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>120</td>
<td>120</td>
<td>120</td>
<td>360</td>
</tr>
<tr>
<td>Total number of procedures for 2 years</td>
<td>682</td>
<td>714</td>
<td>644</td>
<td>2040</td>
</tr>
<tr>
<td>Number of treatments for 2 years per patient (mean) ± SD</td>
<td>5.7 ± 2.5</td>
<td>6.0 ± 2.5</td>
<td>5.4 ± 2.6</td>
<td>5.7 ± 2.6</td>
</tr>
<tr>
<td>Number of weeks with significant improvement for all patients in the study in weeks</td>
<td>7667</td>
<td>7900</td>
<td>8074</td>
<td>23641</td>
</tr>
<tr>
<td>Significant improvement in weeks per procedure (mean) ± SD</td>
<td>10.8 ± 5.7</td>
<td>10.5 ± 5.9</td>
<td>13.2 ± 12.7</td>
<td>11.5 ± 8.8</td>
</tr>
<tr>
<td>Direct procedural costs without drug costs ($)</td>
<td>Physician $85,443</td>
<td>$93,250</td>
<td>$66,342</td>
<td>$245,036</td>
</tr>
<tr>
<td></td>
<td>Facility $216,942</td>
<td>$227,649</td>
<td>$208,994</td>
<td>$653,585</td>
</tr>
<tr>
<td></td>
<td>Total $302,385</td>
<td>$320,899</td>
<td>$275,336</td>
<td>$898,620</td>
</tr>
<tr>
<td>Direct costs per procedure ($)</td>
<td>Physician $125.28</td>
<td>$130.60</td>
<td>$103.02</td>
<td>$120.12</td>
</tr>
<tr>
<td></td>
<td>Facility $318.10</td>
<td>$318.84</td>
<td>$324.52</td>
<td>$320.38</td>
</tr>
<tr>
<td></td>
<td>Total $443.38</td>
<td>$449.44</td>
<td>$427.54</td>
<td>$440.50</td>
</tr>
<tr>
<td>Average total direct costs per patient in 2 years</td>
<td>$2,519.88</td>
<td>$2,674.16</td>
<td>$2,294.47</td>
<td>$2496.17</td>
</tr>
<tr>
<td>Direct procedural improvement in quality of life ($)</td>
<td>$2,050.87</td>
<td>$2,112.25</td>
<td>$1,773.28</td>
<td>$1,976.58</td>
</tr>
<tr>
<td>Indirect costs including drug costs for 1-year improvement in quality of life ($)</td>
<td>$1,374.08</td>
<td>$1,791.68</td>
<td>$1,188.10</td>
<td>$1,324.31</td>
</tr>
<tr>
<td>Total estimated costs including procedural costs, costs of medicine and other indirect costs for 1-year improvement in quality of life ($)</td>
<td>$3,425</td>
<td>$3,527</td>
<td>$2,961</td>
<td>$3,301</td>
</tr>
</tbody>
</table>

Total costs ($) for one-year improvement of quality of life
Cost Utility Analysis of Lumbar Interlaminar Epidural Injections

Effectiveness ratio of less than £20,000 per QALY and an incremental cost effectiveness ratio or threshold of £30,000 per QALY in extenuating circumstances. In the United States, there is no organization such as NICE to calculate cost effectiveness. In fact, many of the regulations derived from ACA, including PCORI state that cost effectiveness is not to be taken into consideration, but to the contrary, cost utility is being used frequently in practice (1-11,82-84).

Multiple limitations of this analysis include consideration of current procedural costs and extrapolation of indirect costs at 40% or multiplication by a factor of 1.67 of direct procedural costs. However, there was no benefit analyzed for return of work even though there was a significant proportion of patients returning to work. Further, the study is derived from a single center assessment of 360 patients, even though this included a large population of chronic pain patients recalcitrant to conservative management incorporating 3 RCTs and assessing long-term improvement. However, these limitations may be considered as advantages. In addition, the cost of provision of epidural injections have decreased in 2017 compared to 2016, which in fact may lower the cost utility with use of 2017 data (85,86).

The costs estimated here are only applicable in a practical pragmatic setting such as described here in private practice with performance of these procedures in an ambulatory surgery setting with reasonable charges (85,86). Consequently, the results of this analysis may not be generalizable to all settings and all populations. Further, it is estimated that cost utility may be 30% to 70% higher in a hospital setting and approximately 20% to 30% lower in an office setting (85,86).

Conclusion

The present analysis of 3 RCTs of lumbar interlaminar epidural injections in a private practice setting in patients after failure of conservative management shows cost utility of epidural injections at $3,301 per QALY. The results also showed cost effectiveness at $3,425 for managing disc herniation, $3,527 for managing discogenic pain, and $2,961 for managing central spinal stenosis with or without steroids with no significant differences observed among the groups or those receiving steroids or those receiving local anesthetic only.

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Appendix Table 1. Employment characteristics of patients in each randomized trial at baseline and at end of 24-month period.

<table>
<thead>
<tr>
<th>Employment status</th>
<th>Disc Herniation</th>
<th>Discogenic Pain</th>
<th>Spinal Stenosis</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline 24 months</td>
<td>Baseline 24 months</td>
<td>Baseline 24 months</td>
<td>Baseline 24 months</td>
</tr>
<tr>
<td>Employed part-time</td>
<td>7 5</td>
<td>10 10</td>
<td>4 2</td>
<td>21 17</td>
</tr>
<tr>
<td>Employed full-time</td>
<td>22 31</td>
<td>16 21</td>
<td>16 26</td>
<td>54 78</td>
</tr>
<tr>
<td>Unemployed</td>
<td>9 6</td>
<td>6 5</td>
<td>10 5</td>
<td>25 16</td>
</tr>
<tr>
<td>Off the work due pain</td>
<td>8 6</td>
<td>4 1</td>
<td>0 0</td>
<td>12 7</td>
</tr>
<tr>
<td>Eligible for employment</td>
<td>46 46</td>
<td>36 36</td>
<td>30 30</td>
<td>112 112</td>
</tr>
<tr>
<td>Total Employed</td>
<td>29 36</td>
<td>26 31</td>
<td>20 28</td>
<td>75 (67%) 95 (85%)*</td>
</tr>
<tr>
<td>Housewife</td>
<td>10 8</td>
<td>10 10</td>
<td>12 10</td>
<td>32 28</td>
</tr>
<tr>
<td>Disabled</td>
<td>54 54</td>
<td>71 70</td>
<td>57 56</td>
<td>182 180</td>
</tr>
<tr>
<td>Over 65 year of age</td>
<td>10 10</td>
<td>3 3</td>
<td>21 21</td>
<td>34 34</td>
</tr>
<tr>
<td>Total Number of Patients</td>
<td>120 120</td>
<td>120 120</td>
<td>120 120</td>
<td>360 360</td>
</tr>
</tbody>
</table>

* significant difference with baseline values (P < 0.001)
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