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A Cost-Effectiveness Analysis of Intradiscal Electrothermal Therapy (IDET) Compared with Circumferential Lumbar Fusion

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Keywords: spinal fusion , cost-effectiveness , discogenic low back pain , intradiscal electrothermal therapy (IDET)

Abstract:

Study Design. Cost-effectiveness analysis

Objective. To evaluate the cost-effectiveness of intradiscal electrothermal therapy (IDET) relative to circumferential lumbar fusion with femoral ring allograft (FRA) in UK.

Summary of Background Data. Circumferential lumbar fusion is an established treatment for discogenic low back pain. However, IDET could be a cost-effective treatment alternative as it can be carried out as a day case.

Methods. Patient-level data were available for patients with discogenic low back pain treated with FRA (n=37) in a randomized trial of FRA vs titanium cage, and for patients recruited to a separate study evaluating the use of IDET (n=85). Both studies were carried out at a single institution in the UK. Patients were followed-up for 24 months, with data collected on low back disability (Oswestry Disability Index), back and leg pain (visual analogue scale), quality of life (SF-36), radiographic evaluations, and NHS resource use. Cost-effectiveness was measured by the incremental cost per quality-adjusted life year (QALY) gained.

Results. Both treatments produced statistically significant improvements in outcome at 24-month follow-up. NHS costs were significantly lower with IDET due to a shorter mean procedure time (377.4 minutes vs 49.9 minutes) and length of stay (7 days vs 1.2 days). At a threshold of £20,000 per QALY, the probability that IDET is cost-effective is high.

Conclusions. Both treatments led to significant improvements in patient outcomes which were sustained for at least 24 months. Costs were lower with IDET, and for appropriate patients IDET is an effective and cost-effective treatment alternative.

Key Words: intradiscal electrothermal therapy (IDET), spinal fusion, cost-effectiveness, discogenic low back pain

Key Points

1. Circumferential lumbar fusion is an established treatment for discogenic low back pain. However, fusion is an invasive surgical procedure. IDET is a minimally invasive procedure which can be carried out on an outpatient basis. In principal, IDET could offer a cost-effective treatment alternative.
2. In two studies involving populations of patients with discogenic low back pain, both circumferential fusion and IDET produced statistically significant improvements in back and leg pain, low back pain disability and quality of life.
3. Treatment costs were significantly lower with IDET because of its shorter procedure time and length of inpatient stay. In appropriate patients, IDET is a cost-effective treatment alternative.

Precis

Cost-effectiveness of intradiscal electrothermal therapy (IDET) is compared with circumferential lumbar fusion in patients with discogenic low back pain. Both treatments produced statistically significant improvements in pain, low back pain disability and quality of life. Treatment costs were significantly lower with IDET, and this is a cost-effective treatment alternative.

Introduction

Experimental and clinical evidence has established that degeneration of the lumbar intervertebral discs is a primary source of refractory low back pain for millions of patients worldwide.[1-4] Discogenic pain may be a result of repetitive injury and subsequent repair mechanisms leading to vascularized and innervated granulation tissue along torn annular fissures.[5-6] A recently published case-control study found that the presence of severe back pathology was associated with two-fold higher odds of having chronic low back pain.[7]

Spinal fusion is an established surgical treatment for discogenic low back pain. McKenna, et al (2005)[8] report results of a randomized controlled trial of two forms of circumferential lumbar fusion using either a femoral ring allograft (FRA) or a titanium cage (TC). On the basis of the results of this trial, Freeman et al (2007)[9] demonstrated the superior cost-effectiveness of FRA from the perspective of the UK National Health Service (NHS). However, because rigid fusion of the spine is invasive and may propagate adjacent-level disc degeneration,[10-11] there has been an impetus to adopt minimally-invasive interventions that preserve the native disc structure and maintain physiologic motion. Intradiscal electrothermal therapy (IDET) (Smith & Nephew, London, UK) is a minimally invasive outpatient procedure in which controlled levels of heat are applied directly to the affected disc by means of a navigable intradiscal catheter. **Regarding mechanism of pain relief, w*e believe that thermal ablation of neoinnervation/ neovascularization of the posterior annulus (as described by Freemont et al) is a plausible explanation*[12]. Due to the fact that** the procedure can be carried out on an outpatient basis, IDET should be less costly than fusion.

A cost-utility analysis has been carried out to evaluate the cost-effectiveness of IDET relative to circumferential lumbar fusion with FRA from the perspective of the NHS. The analysis compares costs to the NHS in the two years following primary intervention and the gain in patient utility between the immediate pre-operative period and two years post-intervention. Cost-effectiveness is measured by the incremental cost per quality-adjusted life year (QALY) gained.

Materials and Methods

Data sources

Patient-level data were available for all of the patients treated with FRA in the single-center trial of FRA vs TC reported by McKenna, et al (2005)[8] carried out at Queen's Medical Centre (QMC), Nottingham. One of the present authors (MPG) was investigator in that study. Seventy-eight randomized patients received treatment with FRA (n=37) or TC (n=41). Inclusion criteria were degenerative disc disease between L3 and S1 with a maximum of two consecutive motion segments to be instrumented, pain or functional deficit pre-operatively for a minimum of 6 months and failure to respond to conservative treatment for at least 3 months. Patients were aged 18-70 years. Diagnostic criteria for inclusion required radiographic evidence of sclerosis, osteophyte formation, degenerative changes of facet joints or greater than 50% collapse of the disc interspace; 3.5 mm or more movement on flexion/extension radiographs; MRI evidence of dehydration of the lumbar disc with or without reactive sclerosis of the adjacent vertebral body; and discographic evidence of abnormal disc morphology with concordant pain on provocation. Exclusion criteria included skeletal immaturity or patients over 70 years, more than two levels involved, previous spinal fusion, spondylolisthesis of Meyerding grade II or greater, active or systemic infection, osteoporosis or the presence of active malignancy.

Patients were followed-up for a minimum of 24 months, with data collected on the Oswestry Disability Index (ODI)[13] measuring the extent of low back pain disability on a scale from 0%-20% (minimal disability) to 100% (bed-bound); Visual Analogue Scale (VAS) measuring back and leg pain severity, scaled from 0 cm (no pain) to 10 cm (worst imaginable pain); the Short-Form 36 (SF-36) measuring quality of life; radiographic evaluations; NHS resource use and employment status. The study ran from February 1998 to October 2002 (inclusive of enrolment and final follow-up).

A separate study to evaluate the use of IDET in patients with chronic discogenic low back pain was carried out at QMC between January 2001 and December 2004. The protocol used was part of a global post-marketing surveillance study initiated by DePuy Spine (Johnson & Johnson, Leeds, UK). All presenting patients meeting the inclusion and exclusion criteria were treated with IDET. Inclusion criteria were symptomatic disc degeneration as demonstrated by concordant pain production with provocative discography at low volume injection (< 1.5 millilitre dye volume) at levels L3/4, L4/5 or L5/S1 without pain reproduction or with discordant pain at adjacent discs; chronic function-limiting low back pain of at least 6 months duration; failure to adequately improve following 8-12 weeks of conservative treatment; lumbar disc degeneration confirmed using MRI with no more than a 50% loss of disc height at the levels to be treated. Exclusion criteria were age <18 years, previous spinal surgery at the levels to be treated, spinal fracture, tumour, retrolisthesis, anterior listhesis, scoliosis, infection, spinal stenosis, spondylolithesis, spondylolysis, large contained or sequestered lumbar disc herniation, evidence of severe disc disruption and insufficient posterior annulus at the level to be treated. Patients were followed-up for a minimum of 24 months and data were collected prospectively on clinical outcomes (ODI, VAS, SF-36), radiographic evaluations and NHS resource use. No information was collected on return to employment. One hundred patients were recruited to the

study. Fifteen patients were excluded from analysis because of protocol violations (previous spinal fusion (4 patients), aged under 18 (1 patient)), missing patient data at baseline (7 patients), and lost to follow-up within 6 months of the IDET procedure (3 patients)). Patient-level data were available for 85 IDET patients.

Patient outcomes

Patient outcomes were measured by changes in VAS pain score, ODI disability rating and health-state utility. Health-state utilities were derived for each patient from SF-36 responses collected at baseline (pre-operatively) and at 6, 12 and 24 months post-operatively, by first converting SF-36 to SF-6D[14] and then applying the coefficients of the SF-6D mean model.[15] Quality adjusted life years (QALY) were calculated using the 'area under the curve' approach.[16]

Resource use and costs

Information on the use of NHS resources was collected for each patient from a review of clinical records and included operating theatre time, procedure-related disposables (catheters, needles and fixators), hospital inpatient stay and subsequent injections for pain relief and surgical interventions related to the original condition (including wound wash-out, debridement, revision surgery for FRA patients and fusion or disc replacement surgery for IDET patients). Resource items were costed at 2005/06 QMC prices or published national average unit costs. For FRA patients, unit costs are those reported in Freeman, et al (2007).[9] Resource items specific to IDET patients (such as catheters and needles) were costed at representative UK prices in 2005/06 supplied by the manufacturer. Costs and utilities were discounted at 3.5% in line with recommendations of the National Institute for Health and Clinical Excellence (NICE, 2008).[17]

Missing data treatment

For patients in the FRA group, information was missing on theatre time (2/37 patients) for the primary fusion operation and length of stay for 2/7 patients who underwent a revision procedure. For IDET patients information was missing on the number of catheters used during the initial procedure (7/85 patients), and on implants used (2/18), theatre time (3/18) and length of stay (2/18) for patients undergoing subsequent procedures.

Utility scores (Table 1) were available for 95% (36/37) of FRA patients at baseline and at the 24-month follow-up. Information was missing for 18.9% of patients at 6 months (7/37), and for 13.5% (5/37) at 12 months. These patients either did not attend a particular follow-up appointment or failed to complete the SF-36 questionnaire. None withdrew or was lost to follow-up. In the IDET group, utility information was available for 96% (82/85) of patients at baseline and for 84.7% (72/85) at 6 months. Missing information was due to the patient failing to attend the 6-month follow-up appointment, or failing to complete the SF-36. Between 6 months and 12 months, 7 patients were

lost to follow-up and 6 patients withdrew from the study, so that at the 12-month assessment utility information was available for 78.8% (67/85). Between 12 months and 24 months, 12 further patients were lost to follow-up, 13 withdrew and one patient failed to complete the SF-36. At the 24-month assessment, utility information was available for 54% (46/85) of IDET patients.

Patients were withdrawn from the IDET study if the patient and surgeon mutually agreed that the procedure had been unsuccessful (as evidenced by persistent pain and disability). Nineteen patients withdrew from the study between 6 and 24 months. Information was available for 18 of these patients on the costs of all subsequent interventions (injections or surgery), and these patients were included in the costing analysis. However, patients who withdrew did not complete quality of life assessments after that point, and no subsequent utility data were available for these patients.

Three scenarios were constructed to handle missing resource use and utility information. In the base case analysis, missing data were imputed on the basis of the *mean* observed value of costs or utilities for each group at the respective time point. Two extreme cases were also considered in which missing data were imputed at the *minimum* or *maximum* of observed values.

Data analysis

The mean difference in costs and QALYs between the two intervention groups, and bias corrected and adjusted 95% confidence intervals were estimated using non-parametric bootstrapping.[18]

Results

Patient characteristics

The patient groups were similar in age (mean 39.5 years (FRA) vs 42.3 years (IDET)) and gender (54% female in both groups). The mean pre-treatment VAS score was significantly higher in the FRA group, indicating greater pain severity (7.0 (FRA) vs 5.6 (IDET); p=0.0016). The mean pre-treatment ODI score was also significantly higher in the FRA group (56.5% (FRA) vs 48.2% (IDET); p=0.0079). Mean duration of symptoms was 73 months for the IDET group and 87 months for the FRA group (not significant, p=0.472). There were no significant differences between the groups in SF-36 domain scores, except physical function (p=0.004) and mental health (p=0.021), both of which were lower in the FRA group, indicating lower quality of life. Baseline utility scores were significantly lower in the FRA group (0.48 vs 0.52, p=0.03) (Table 1 and Fig 1).

Outcomes

There was no significant difference in re-intervention rates between the two treatments (p=0.1354). The re-intervention rate in the FRA treatment group was 32% (12/37). Five patients (14%) required injections for pain relief, seven (19%) required some form of additional surgical intervention including three (8%) requiring a revision fusion procedure. In the IDET group, the re-intervention rate was 47% (40/85). Twenty-six patients (31%) required injections for pain relief and 18 patients (21%) required some form of surgical intervention, of which 12 required disc replacement or primary fusion (14%). Four patients required both injections and surgical intervention.

Mean VAS was reduced in both treatment groups between the pre-treatment period and the 24-month follow-up: from 5.6 pre-treatment to 4.1 (IDET; p=0.001)), and from 7.2 pre-treatment to 5.2 (FRA; p<0.001)). The difference between the two groups at 24-months was not significant. (p=0.0877). Both groups experienced an improvement in low back pain disability (ODI) at 24-months: from 48.2% ('severe disability') to 37.4% ('moderate disability') in the IDET group (p<0.001), and from 56.5% ('severe disability') to 42.0% ('severe disability') in the FRA group (p<0.001). The difference between the two treatment groups at 24-months was not significant (p=0.3813).

Both treatment groups experienced a statistically significant increase in utility between the pre-operative assessment and 24-months post intervention (p<0.001 (IDET); p=0.002 (FRA)) (Table 1 & Figure 1). In the IDET group, most of the utility gain was achieved in the first 6 months post-intervention (0.50 to 0.60) and was sustained to 24-months. In the fusion group the maximum utility gain was achieved at 12 months (0.48 to 0.64) and there was some reduction in utility between the 12 and 24-month assessments (0.64 to 0.58). The absolute increment in utility was the same for both treatment groups.

Cost-effectiveness

NHS costs were lower with IDET irrespective of the method of imputing missing values, primarily due to the shorter procedure time and length of stay associated with the IDET procedure. Mean (primary) procedure time per patient was 377.4 minutes (FRA) compared with 49.9 minutes (IDET), and mean length of stay was 7.0 days (FRA) vs 1.2 days (IDET). Even including all subsequent surgical interventions, procedure time and length of stay remained shorter in the IDET group.

The cost difference between IDET and FRA was not sensitive to the method of imputation. The difference in QALY gains was more sensitive to the method of imputation because of the relatively greater amount of missing information on utility, particularly in the IDET group (Table 2). The following points summarize the major findings of each imputation method:

- Imputing missing values at the *mean* of observed values, IDET is a dominant treatment option. The mean incremental cost of IDET was -£3,713 per patient (95% CI = -£2,684 to -£4,742) and the mean incremental QALY gain, adjusted for baseline utility scores, was 0.03 (95% CI = -0.07 to 0.12). At a threshold of £20,000 per QALY the probability that IDET is cost-effective is 1, and the net health benefit is 0.21 QALY per patient treated. At £30,000 per QALY the probability is 0.99 and net health benefit is 0.15 QALY.

- Imputing at *minimum* values, the incremental cost of IDET was -£3,712 (95% CI = -£2,719 to -£4,707) and the adjusted incremental QALY gain was –0.05 (95% CI = -0.16 to 0.057). The incremental cost of fusion was £74,200 per QALY (£3,712/0.05). At a threshold of £20,000 per QALY the probability that IDET is cost-effective is 1, and the net health benefit is 0.14 QALY per patient treated. At £30,000 per QALY the probability is 0.99 and net health benefit is 0.08 QALY.

- Imputing at *maximum values*, IDET is dominant. The incremental cost of IDET was -£3,657 (95% CI = -£2510 to -£4,802) and the expected QALY gain was 0.11 (95% CI = 0.01 to 0.22). At a threshold of £20,000 per QALY the probability that IDET is cost-effective is 1, and the net health benefit is 0.3 QALY per patient treated. At £30,000 per QALY the probability is 1 and net health benefit is 0.23 QALY.

Figure 2 shows incremental QALYs and cost per patient resulting from a decision to select IDET rather than FRA, using the mean imputation method. The expected cost saving with IDET was £3,713 per patient (95% CI = £2,684 to £4,742) and the mean QALY gain was 0.03 per patient (95% CI = -0.07 to 0.12). IDET is a dominant treatment option.

Discussion

Both of the treatments considered in this analysis were effective in relieving the symptoms associated with discogenic low back pain. Both treatments produced statistically significant improvements in back and leg pain, low back pain disability and health-state utility compared with the pre-intervention assessment. Most of the improvement was sustained for at least 2 years. Neither procedure was completely successful in all patients. Overall re-intervention rates were 32% for the FRA group and 47% for the IDET group (p=0.1354). However, most patients required only one subsequent injection for pain relief and the numbers requiring an additional surgical procedure were relatively low: 19% in the FRA treatment group and 21% in the IDET group.

Expected costs to the NHS were £3,261 per patient in the IDET group and £6,974 for patients in the FRA group (Table 2). This includes the cost of re-intervention (and/or the cost of other treatments for the patients who were withdrawn from IDET for lack of treatment efficacy. Costs were still lower with IDET, despite a slightly higher re-intervention rate, because IDET is a less invasive procedure which can normally be carried out on an outpatient or day-case basis. Average procedure time and post-operative length of stay were both shorter in the IDET group

There are several reasons for the delay in reporting these results. When initially presented at spinal surgical meetings there was scepticism regarding the utility of IDET. The biggest challenge was that any observed treatment effect wound not be maintained or overtaken by progressive disc degeneration. To counter this critique, the senior surgical author resolved to delay publication to allow an opportunity for 'failed' IDETs to return to the regional centre. There was only one patient who returned 4 years after an initially successful IDET. A repeat MRI did not show any significant accelerated disc failure at the index level. Unfortunately, there is no comparable fusion data to allow meaningful comparison with IDET> Despite and perhaps because of the conclusions from this study it has not well received in the established spine surgical journals. Despite the time lapse, the relative costs of the additional procedures remain the same. The historical inflation rate over this period has averaged 3% per annum.

Compared with a 'no intervention' baseline, the incremental cost per QALY gained with IDET was approximately £15,500. Expected QALYs in the two years post-baseline were 1.02 (no intervention) and 1.23 (IDET), an overall gain of 0.21 QALY over the two years with IDET. The expected cost of IDET was £3,261 and the incremental cost per QALY gained was therefore £15,500 (£3,261/0.21). At an implicit threshold of £20k-£30k per QALY, there is a high probability that IDET is cost-effective. On the same basis, the incremental cost per QALY gained with FRA would be £33,200 (£6,974/0.21). The 'no intervention' baseline assumes no change in utility from baseline and no costs to the NHS, which is conservative.

Comparing IDET and FRA directly, IDET is dominant because expected costs are lower (the mean difference per patient was -£3,713) for a similar improvement in quality-adjusted life years (the mean difference in favour of IDET was 0.03, but this difference was not statistically significant). A direct comparison between the two treatments is complicated by the fact that the two patient groups were drawn from separate trials, rather than from a single randomized study with contemporaneous recruitment. IDET was introduced at QMC in January 2001 and was not available to patients during the period of recruitment into the FRA study (February 1998 to October 2000). However, fusion surgery was a treatment option for patients who did not meet the criteria for IDET. The mean ages of patients in the two studies were similar, but the FRA group appeared to have more severe symptoms at baseline as evidenced by differences in pre-treatment VAS, ODI and utility scores. Inclusion and exclusion criteria were similar for both of the studies, with two exceptions: loss of disc height and inclusion of spondylolisthesis. Patients included in the FRA trial had to have loss of disc height of 50% or more, whereas patients with more than 50% loss of disc height were excluded from receiving IDET. This may indicate that FRA patients had more advanced disc degeneration, although there is no necessary correlation between disc degeneration and the extent of disability. This does not, in our view, represents significant bias between the two treatment modalities. Spondylolisthesis (up to Meyerding grade I) was allowed in the FRA trial while patients with any spondylolisthesis were not eligible for IDET.

No FRA patients were lost to follow-up or were withdrawn from the study. In the IDET group, 9 patients were lost to follow-up. Resource use and utility data were available for these patients up to the point at which they were lost to follow-up. A further 19 patients were withdrawn from the study because the procedure was not successful. Information was available for 18 of these patients on resource use, but not on quality of life. **Inputting** utility scores for these patients on the basis of the mean values observed in the IDET group may overestimate utility gains, although it is important to note that most of the utility gain in the IDET group was achieved by the 6-month assessment. Further research would be valuable to confirm the utility gains associated with the IDET procedure. **Overall, IDET costs less than FRA and is more QALY efficient with expected further reduction of IDET costs as it does not appear that surgical costs have been reduced over time.**

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Table 1: Utility scores

	Fusion		IDET	
	Observations	Mean value	Observations	Mean value
Pre-operative	36	0.48	82	0.52
6-months	30	0.58	72	0.60
12-months	32	0.64	67	0.60
24-months	36	0.58	46	0.62

Table 2: Expected costs and QALYs

Imputation method	Treatment group	Expected cost (per patient)	Expected QALY (per patient) unadjusted	ICER
Mean	IDET	£3261	1.23	Dominant
	Fusion	£6974	1.16	-
Min	IDET	£3140	1.08	-
	Fusion	£6852	1.09	£74,200*
Max	IDET	£3550	1.39	Dominant
	Fusion	£7207	1.23	-

* calculated on parameter estimates adjusted for baseline utility scores

Figure 1: Utility scores at baseline, 6, 12 and 24 months

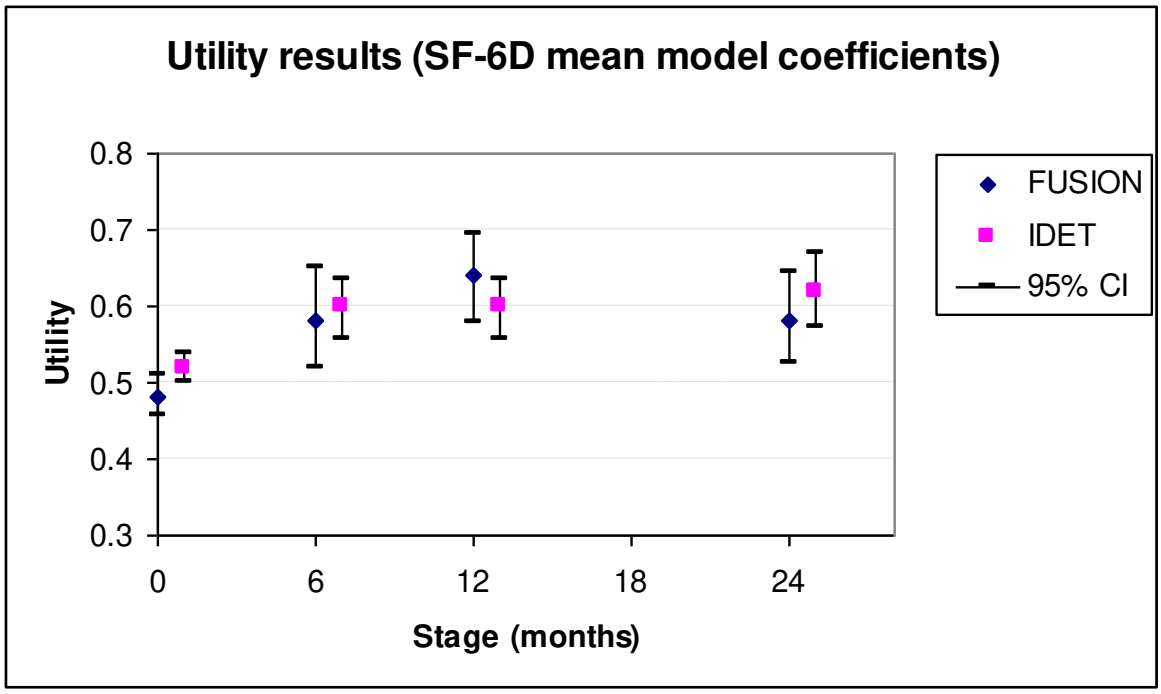

Figure 2: Incremental cost and incremental QALY (IDET-FRA), mean imputation method. This figure shows that for similar degrees of effectiveness, IDET is less costly than FRA.

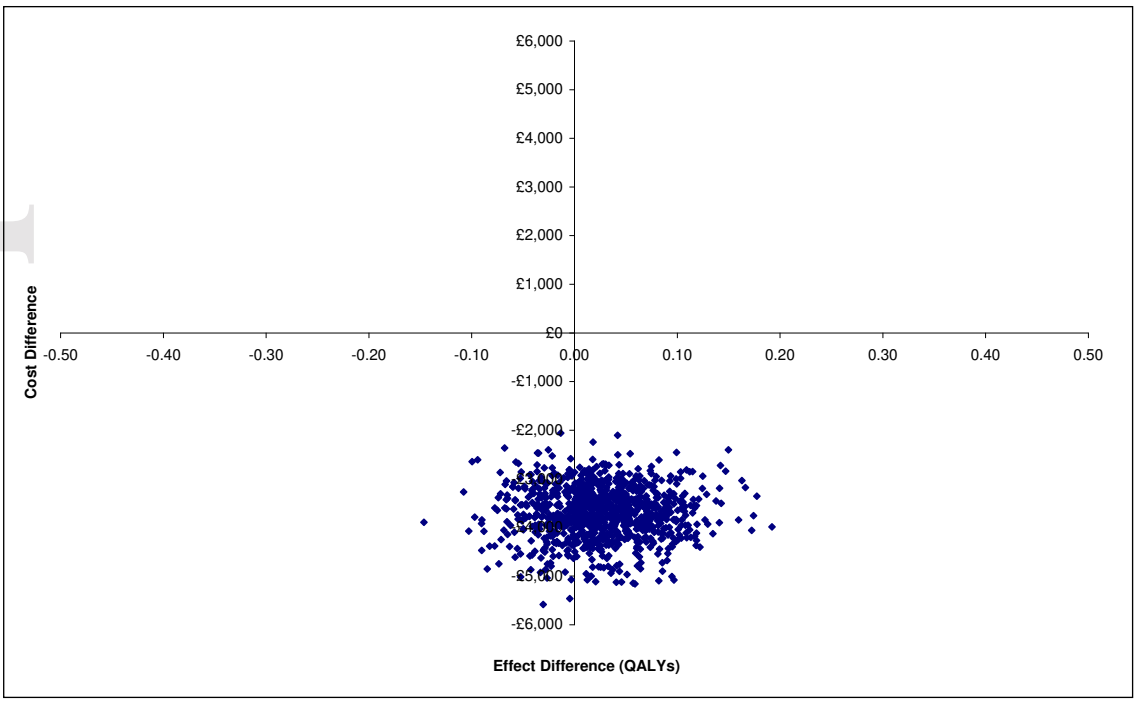

Figure 3: Pie chart demonstrating percentage of other interventions needed after FRA.

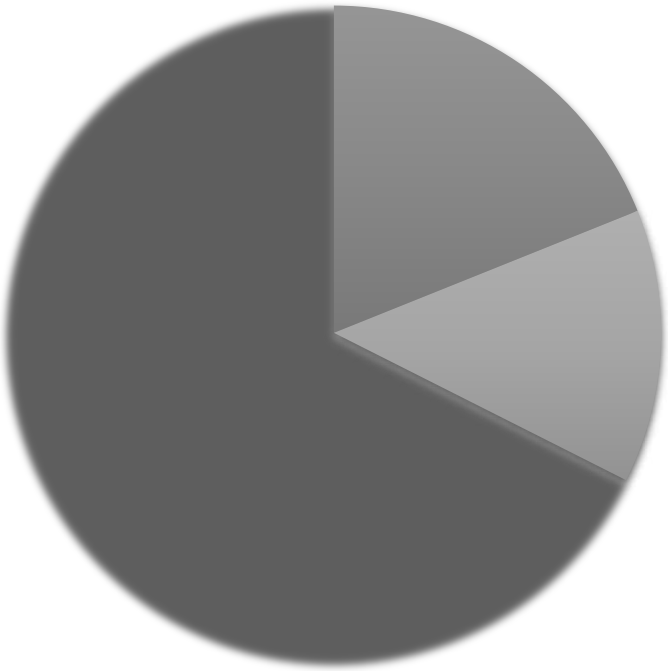

Figure 4: Pie chart demonstrating other interventions needed after IDET