ARTICLE

Quality of life after out of hospital interventional orthopaedic & regenerative medicine procedures in an integrated service delivery model

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Abstract

Background & Aim: Out of hospital interventional orthopaedic and regenerative medicine (IORM) procedures are a new addition to the subspecialty of interventional radiology. This study aimed to assess health outcomes following IORM procedures in an outpatient integrated service delivery model in clinical practice.

Methods: Retrospective study of all patients who completed the pre- and post-procedure EuroQol 5D5L questionnaire over a 6 month period.

Results: Forty-eight patients (age range=32-89, mean=60.5, median=63.5 years) were eligible. Mean and median pre-treatment EQ5D5L index values of 0.53 and 0.61 (range: -0.248 to 0.879, SD: 0.28, 95% CI: [0.45, 0.61]) improved to 0.73 and 0.73 (range: 0.414-1.0; SD: 0.13, 95% CI [0.69, 0.76]) (p < 0.01, Cohen 'd' = 0.93) post-treatment. Improvements in ‘no problems’ in each health dimension were: pain (mathematical infinity), mobility (109%), usual activities (137.5%), self-care (56%), anxiety/depression (23.3%). Reductions in ‘any problems’ in each dimension of health were: pain (-14.5%), mobility (-32%), self-care (-60.87%), anxiety/depression (-38.8%). Pre-treatment, a strong negative correlation between EQ5D5L index values versus mobility levels (r = -0.67, p < 0.01) and versus usual activities (r = -0.62, p < 0.01) was present. Post-treatment, a strong negative correlation between EQ5D5L index scores versus pain level (r = -0.68, p < 0.01) and versus mobility (r = -0.75, p <0.01) was present.

Conclusion: Significant improvements in all health dimensions with a large treatment effect was shown following outpatient IORM procedures in an integrated interventional radiology service delivery model. Improvements in mobility and pain were the most important determinants of health.

Keywords
Dimensions of health, integrated practice units, integrated service delivery, interventional orthopaedic and regenerative medicine (IORM), interventional radiology, optimal patient outcomes, patient reported outcome measures (PROMs), person-centered healthcare, quality of life, value-based health services

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Accepted for publication: 18 January 2018

Introduction

Interventional orthopaedic and regenerative medicine (IORM) procedures are a new addition to the practice of interventional radiology (IR). IORM is a bridging speciality incorporating (a) core skill sets within medicine with a requirement on cross medical speciality expertise, for example, diagnostic and interventional radiology, orthopaedics, pain management [1], (b) a service beyond the boundaries of basic professional training, for example, clinical medicine and physical therapy, (c) regenerative/ablative techniques and (d) laboratory sciences (see Appendix 1).

IORM procedures are usually performed instead of surgery and do not require overnight hospital admissions. IORM is in a state of infancy with the possibility of a predicted explosion of use in the future due to the perceived clinical benefits of interventional regenerative medicine coupled with the inability of traditional orthopaedics, spinal surgery and pain medicine to meet escalating service needs [2]. It is imperative for practitioners of IORM to set high standards in service delivery to achieve the best patient outcomes. This will ensure that IORM stands the test of time by providing safe, high quality services that improve the health of patients and which provide value in terms of health expenditure. The choice of outcome measures in chronic non-fatal conditions that are usually treated by IORM procedures should reflect organ/condition specific function and quality of life (QoL). There is a shift away from practitioner-
reported efficacy measures (e.g., reduction in size of tumour post-treatment, Constant Score for shoulder), towards patient-reported outcome measures (PROMs) in the assessment of healthcare interventions. PROMs are subjective evaluations by patients on their function and health [3]. PROMs may include condition-specific outcome measures (e.g., knee, shoulder function) or quality of life (QoL) assessments (e.g., EuroQol - European Quality of Life Instrument). Condition-specific PROMs do not capture information required to assess health status and are inherently designed to assess healthcare intervention.

For example, while condition-specific PROMs of knee or hip function measure absence of joint infirmity, they do not measure dimensions of health such as anxiety/depression and self-care and do not entirely capture the WHO definition: ‘Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’ [4]. Therefore, QoL assessments that provide information on ‘health’ are considered more important than measures that provide information on ‘healthcare’ [5]. This paper describes the improvement in health that resulted from an outpatient integrated service model in an interventional radiology practice performing IORM procedures.

**Method**

**EuroQol(EQ) 5D-5L Forms**

This is a retrospective analysis of pre- and post-QoL forms completed during routine clinical practice. Following an institutional policy implementation to improve standards of care, patients completed the EQ5D5L (EuroQol, Rotterdam, The Netherlands) written paper instrument, a validated health outcome tool [6]. The first component of the EQ5D5L contains descriptive dimensions of health: mobility, self-care, usual activities, pain and anxiety/depression. Patients select one of 5 levels for each health dimension with an assigned numerical code: no problems = 1, slight problems = 2, moderate problems = 3, severe problems = 4 and extreme problems/unable to do = 5. This generates a 5-digit number called a ‘profile score’. The profile score is referred to a data set of values designated for normal populations from various countries [7]. A person who selects ‘no problems’, ‘slight problems’, ‘moderate problems’, ‘severe problems’ and ‘unable to do’ for each dimension of health generates a profile score of 12345. This profile of 12345 is referred to the dataset that lists country specific EQ5D5L index values: a value of 0.346 is assigned for a patient from Germany; 0.087 is assigned for a patient from The Netherlands; 0.063 is assigned for a patient from the UK. A patient who marks ‘no problems’ for all 5 dimensions generates a profile score of ‘11111’ - that is assigned an index value of ‘1’ representing the best possible health.

The second component of the EQ5D5L is the Visual Analogue Score (VAS). Patients mark an ‘x’ on a 20 cm vertical scale with the ends of the scale marked as 0 (worst health imaginable) to 100 (best health imaginable). They write the corresponding numerical in a box near the scale. For example, if they felt their state of health on the day was 60%, they would mark a cross on the scale at ‘60’ and also write the number ‘60’ in the box next to the scale.

EQ5D5L paper forms were completed by patients from September 2016 at the institution of study before an IORM procedure and at 3 months follow-up. Forms were completed by patients themselves following a brief instruction to ensure conformity as per EuroQol guidelines. Completed questionnaires were scanned and saved into the practice management software Genie (Genie Solutions Pty Ltd, PO Box 85, Indooroopilly Qld 4068). Data for analysis were from those patients who had completed both the index scores of the descriptive system (value sets from the 5 dimensions of health), VAS (see Tables 1 & 2) and only if the forms were completed as per the vendors instructions [8]. Permission to use the paper format of EQ5D5L was sought from EuroQol, Rotterdam, The Netherlands (Registration ID: 20250).

**Table 1 Patient Demographics**

<table>
<thead>
<tr>
<th>No. of Patients (Male/ Female)</th>
<th>Number</th>
<th>Mean/Median</th>
<th>Range (Standard Deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>48</td>
<td>60.54 / 63.5 years</td>
<td>32.89 (11.63)</td>
</tr>
<tr>
<td>Smokers</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Prior Psychological History /Treatment</td>
<td>5</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Ethical approval and informed consent**

Ethics approval was not deemed necessary as the data were for the purpose of quality control in routine clinical practice. This is a retrospective analysis of information gathered during routine clinical practice. No patient was allocated any treatment. All patients chose to have their treatment and procedures were performed after full informed consent explaining the risks, potential benefits of treatment in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Data selection**

Search results returned 124 adult patients who completed EQ5D5L forms between September 2016 and April 2017. Fifty-four patients had completed pre- and post-procedure EQ5D5L forms. One patient completed 2 forms as both knees were treated. The worse of the 2 knees was selected for analysis. One patient had an injury post-treatment and was excluded from the analysis. The following were not eligible to be selected as they had filled the forms incorrectly: 3 patients had either ticked between levels or ticked more than one level under one of the dimensions; another patient did not complete any of the questions under health dimensions. Forty-eight patients with completed
### Table 2 Conditions treated

<table>
<thead>
<tr>
<th>Condition</th>
<th>No: of Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee Osteoarthritis</td>
<td>26 (54)</td>
</tr>
<tr>
<td>Hip Osteoarthritis</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Ankle Osteoarthritis</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Peroneus Longus Tendinosis/Os Peroneum</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Disc herniation &amp; sciatica</td>
<td>2 (4.1)</td>
</tr>
<tr>
<td>Post-traumatic neuropathic pain</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Rotator cuff disease &amp; tears</td>
<td>4 (8.3)</td>
</tr>
<tr>
<td>Tennis /Golfers Elbow</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Low Back Pain &amp; Disc Degeneration &amp; no prior surgery</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Sciatica from disc herniation</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Failed Back Surgery Syndrome</td>
<td>2 (4.1)</td>
</tr>
<tr>
<td>Hamstrings/Adductor Origin Tendinosis</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Gluteal Tendon Degeneration/Tear</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Thumb Metacarpophalangeal joint psoriatic arthritis</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Talonavicular Arthritis</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Cervical Facet Arthritis</td>
<td>1 (2)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>48</strong></td>
</tr>
</tbody>
</table>

### Table 3 Correlation of Pre-treatment Health Dimension Levels versus EuroQol 5D5L Health Outcome Scores

<table>
<thead>
<tr>
<th>Pre-treatment EQL Index Value</th>
<th>Pre-treatment VAS Score</th>
<th>Pre-treatment EQL Index Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-treatment EQL Visual Analogue Score</td>
<td>( r = 0.4 ) ( p = 0.01 )</td>
<td>-</td>
</tr>
<tr>
<td>Pre-treatment Mobility Level</td>
<td>( r = -0.33 ) ( p = 0.05 )</td>
<td>( r = -0.67 ) ( p &lt; 0.01 )</td>
</tr>
<tr>
<td>Pre-treatment Self Care Level</td>
<td>( r = -0.31 ) ( p = 0.05 )</td>
<td>( r = -0.43 ) ( p &lt; 0.01 )</td>
</tr>
<tr>
<td>Pre-treatment Usual Activities Level</td>
<td>( r = -0.26 ) ( p &lt; 0.5 )</td>
<td>( r = -0.62 ) ( p &lt; 0.01 )</td>
</tr>
<tr>
<td>Pre-treatment Pain Level</td>
<td>( r = -0.3 ) ( p &lt; 0.05 )</td>
<td>( r = -0.4 ) ( p &lt; 0.01 )</td>
</tr>
<tr>
<td>Pre-treatment Anxiety Depression Level</td>
<td>( r = -0.4 ) ( p &lt; 0.01 )</td>
<td>( r = -0.41 ) ( p &lt; 0.01 )</td>
</tr>
</tbody>
</table>

\( r \) is the correlation coefficient

<table>
<thead>
<tr>
<th>Value</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0 - 0.19</td>
<td>“very weak”</td>
</tr>
<tr>
<td>0.2 - 0.39</td>
<td>“weak”</td>
</tr>
<tr>
<td>0.4 - 0.59</td>
<td>“moderate”</td>
</tr>
<tr>
<td>0.6 - 0.79</td>
<td>“strong”</td>
</tr>
<tr>
<td>0.8 - 1</td>
<td>“very strong”</td>
</tr>
</tbody>
</table>

\[33\]
Table 4 Correlation of Post-treatment Health Dimension Levels versus EuroQol 5D5L Health Outcome Scores

<table>
<thead>
<tr>
<th></th>
<th>Post-treatment VAS</th>
<th>Post-treatment Index Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-treatment EQL Index value</td>
<td>$r = 0.4$ (p &lt; 0.01)</td>
<td>-</td>
</tr>
<tr>
<td>Post-treatment EQL VAS</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Post-treatment Mobility Level</td>
<td>$r = -0.31$ (p &lt; 0.05)</td>
<td>$r = -0.75$ (p &lt; 0.01)</td>
</tr>
<tr>
<td>Post-treatment EQL Visual Analogue Level</td>
<td>$r = -0.33$ (p &lt; 0.05)</td>
<td>$r = -0.57$ (p &lt; 0.01)</td>
</tr>
<tr>
<td>Post-treatment Usual Activities Level</td>
<td>$r = -0.29$ (p &lt; 0.05)</td>
<td>$r = -0.59$ (p &lt; 0.01)</td>
</tr>
<tr>
<td>Post-treatment Pain Level</td>
<td>$r = -0.29$ (p &lt; 0.05)</td>
<td>$r = -0.68$ (p &lt; 0.01)</td>
</tr>
<tr>
<td>Post-treatment Anxiety Depression Level</td>
<td>$r = -0.26$ (p &lt; 0.5)</td>
<td>$r = -0.43$ (p &lt; 0.01)</td>
</tr>
</tbody>
</table>

‘$r$’ is the correlation coefficient
0 - 0.19 - “very weak”
0.2 - 0.39 - “weak”
0.4 - 0.59 - “moderate”
0.6 - 0.79 - “strong”
0.8 - 1 - “very strong” [33]

Figure 1 Pre- and Post-IORM procedure Euroqol 5D5L Index Scores

![Graph showing Euroqol 5D5L Index Scores](image)

Figure 2 Pre- and Post-IORM procedure Euroqol VAS Scores

![Graph showing Euroqol VAS Scores](image)

Paired pre- and post-EQ5D5L forms were eligible for the final analysis. Five patients had both knees treated and filled one set of forms for both knees. On the basis that the study population was similar in ancestry to those from the United Kingdom, the EQ5D5L index value sets for a population from the United Kingdom was employed in this research.
Data Analysis

The profile level of each dimension of health was assessed before and after IORM. ‘No problems’ (level 1) were compared to ‘any problems’ (level 2, 3, 4, 5) for each health dimension. The EQ5D5L index values and VAS scores were analysed pre- and post-treatment. A two-way Students ‘T’ test was used to assess the ‘p’ value for statistical significance of any difference between pre- and post-treatment EQ5D5L index and VAS scores.

Cohen ‘d’ value calculation assessed the magnitude of effect by dividing the difference between mean pre- and post-treatment EQ5D5L index and VAS scores and divided by the pooled standard deviation respectively [9]. Effect of treatment was assessed by Cohen ‘d’ as follows: \( ≥ 0.8 = \text{large}; \) \( > 0.2 \text{ to } < 0.8 = \text{medium}; \) \( ≤ 0.2 = \text{small}. \)

A single sample confidence interval calculator using a ‘t’ statistic and sample mean was used to generate an interval estimate for a population mean [10]. Spearman’s rank correlation test with a two-tailed test was used to test the strength and direction of correlation between the individual dimensions of health versus the index values and VAS scores before and after treatment (see Tables 3 & 4) [11], with reference values as follows: 0-0.19 = “very weak”; 0.2-0.39 = “weak”; 0.4-0.59 = “moderate”; 0.6-0.79 = “strong”; 0.8-1 = “very strong”.

Results

Table 1 and Table 2 show patient age and conditions treated, 68.7% of patients suffered a form of arthritis, 16.6% had tendon lesions, 12.5% had lumbar disc lesions and 2% had post-traumatic neuropathic pain. Mean and median pre-treatment EQ5D5L index values of 0.53 and 0.61 (range: -0.248 to 0.879, SD: 0.28, 95% CI [0.45, 0.61]) improved to 0.73 and 0.73 (range: 0.414-1; SD: 0.13, 95% CI [0.69, 0.76]) \( (p < 0.01, \text{Cohen ‘d’} = 0.93) \) (Figure 1), respectively, post-treatment. The mean and median pre-treatment EQ5D5L VAS score of 75/100 and 80/100 (range: 5-98/100, SD:19/100, 95% CI [69.6, 80.45]) improved to 81/100 and 80/100 (range: 35-100/100, SD: 11.7/100, 95% CI [77.52, 84.48]) \( (p < 0.01, \text{Cohen ‘d’} = 0.38) \) (Figure 2), respectively, post-treatment. There was a moderate correlation between pre- and post-treatment EQ5D5L index values and VAS scores \( (r = 0.4, \ p < 0.01). \) There were no complications during the study period: no patient was admitted to hospitals or commenced on antibiotics post-IORM procedures.

There was an increase in the number of patients with ‘no problems’ and a decrease in the number of patients with ‘any problems’ in all 5 dimensions of health before and after IORM (Figure 3 a-e). It was mathematically impossible to calculate improvements to ‘no problems’ with pain (due to numerical infinity). Figure 4 a-e shows changes in each of the 5 levels of problems for individual health dimensions.
Correlations of Health Dimensions before IORM procedures

A strong negative correlation between pre-IORM mobility levels and EQ5D5L index values ($r = -0.67, p < 0.01$) and a strong negative correlation between pre-IORM usual activities level and EQ5D5L index values ($r = -0.62, p < 0.01$), were shown (see Table 3).

Correlations of Health Dimensions after IORM procedures

At post-procedure follow-up, there was a strong negative correlation between pain level and EQ5D5L index scores ($r = -0.68, p < 0.01$) and a strong negative correlation between mobility level and EQ5D5L scores ($r = -0.75, p < 0.01$) (see Table 4).

Discussion

Health outcomes following IORM procedures showed a large treatment effect with statistically significant ($p < 0.01$) improvements in all five dimensions of health. The improvements in VAS after IORM procedures showed a medium treatment effect that was statistically significant. There was a strong correlation between individual dimensions of ‘mobility’, ‘pain’ and ‘usual activities’ to overall health status. This is in keeping with the nature of affliction caused by chronic orthopaedic disorders that were treated - that is, mobility, pain and usual activities.

First, a strong correlation between mobility and health outcome before and after IORM procedures suggests that patients’ views on their overall health is a function of their ability to mobilise. Following IORM procedures, the number of patients with ‘no problems’ in mobility doubled (from 11 to 23 patients). Also, the number of patients with ‘any problems’ in mobility reduced from 37 to 25. Impairment in physical activity and mobility are risk factors for disability and death. The Evergreen project from Finland is an eight year follow-up study on 1,109 adults (65 to 84 years) that ranked the importance of patient ‘mobility’ versus ‘physical activity’ [12]. The relative risk of death was three times greater in those who were sedentary with a mobility impairment in comparison to those who were physically active despite a mobility impairment. Although it would be intuitive to assume that physical activity is a function of mobility, the difference in health outcomes appears to relate more to the physical inability to be mobile, rather than the lack of intention to be physically active. In the current study, patients with mobility impairment were identified and treated with IORM prior to a prescription of exercises. On the other hand, those who led a sedentary life style without a mobility impairment were given a prescription of activities instead of a prescription of an IORM procedure.

Mobility, physical performance and systemic inflammation are linked. The InCHIANTI study, a prospective population-based Italian study of older people, showed that inflammation (measured as high levels of interleukin 6 (IL-6), C reactive protein (CRP), and interleukin-1 receptor antagonist (IL-1RA)) is significantly associated with poor physical performance and muscle strength in older persons [13]. The Chingford Study, a prospective population-based study of healthy, middle-aged British women, showed that increased circulating levels of IL-6 was associated with the development of radiographic knee osteoarthritis [14]. Arthritis-related reduced physical activity has been suggested as an additional barrier in the effective management of heart disease [15]. Evidence suggests a biological basis for links between reduced mobility, systemic inflammation, chronic diseases and the status of long term health. Not surprisingly, normal mobility and physical activity have been shown to have a favourable impact on long term impact of diabetes and cardiovascular disease [16].
Figure 4a Changes in Mobility for all 5 levels of outcome

Figure 4b Changes in Self-care for all 5 levels of outcome

Figure 4c Changes in Usual Activities for all 5 levels of outcome
Second, there was a strong correlation between reduction in pain and improved health index score following IORM procedures. Prior to IORM procedures, there was no patient who had ‘no problem’ with pain. Post-IORM procedures, there were seven patients who reported ‘no problems’ with pain (% improvement was impossible to calculate due to mathematical infinity). Following IORM procedures, all three patients with prior extreme levels of pain had reduced levels of pain. IORM procedures are specifically performed into pain generating tissues, such as diseased tendons, cartilage or nerves with the aim of addressing abnormal biology - particularly progressive degeneration, inflammation and a state of tissue catabolism. Improvements in pain and overall health after IORM procedures validate the objective to directly treat abnormal underlying biology that causes pain.

Third, there was a strong correlation between reduced ability to perform usual activities and poor health index scores prior to IORM procedures. After IORM procedures, more than twice the number of patients were able to perform their usual activities with ‘no problems’. Also, the number of patients with ‘any problems’ performing their usual activities reduced by one third after IORM procedures. Also, the number of patients with no problems in self-care improved by 56% and those with any problems in self-care reduced by 60%. The ability to perform usual activities and self-care suggests that patients may have been less dependant post-IORM procedures in this study.

Surprisingly, levels of anxiety/depression improved after IORM procedures, 23.3% more patients reported no problems and 38% had less problems with anxiety/depression post-IORM procedures. Increased pain has been associated with depression in knee osteoarthritis [17]. Reducing depression is crucial because patients with depression in chronic medical conditions including arthritis are at risk of suicide [18,19]. Loss of independence or mobility due to pain decreased an individual’s participation in social activities and increased the risk of depression significantly [20]. It appears that beyond a co-morbid condition, depression and chronic pain worsen morbidity and mortality [21] to the extent that a mechanism through the inflammatory pathway with cross-links to depression, pain and arthritic conditions has been shown in previous studies. Chronic pain with increased levels of tumour necrosis factor-α is a risk factor for depression in patients with rheumatoid arthritis [22]. Treatment response to antidepressant medication is reduced in patients with increased levels of inflammatory biomarkers [23]. Anti-inflammatory medications reduce depressive symptoms via the COX 1 and COX 2 inflammatory pathways [24,25]. In the current study, a similar mechanism that reduced depression directly via inflammatory pathways is
postulated due to the inherent anti-inflammatory effect of autologous blood derived growth factors [26]. Improvements in mobility and betterment in depression in the current study may also be attributed to the neurobiological effect of improved mobility/physical activity on neuroplasticity substrates in depression through various mechanisms, including telomere length, adaptive epigenetic signalling, anti-oxidant defence, dopamine levels, synaptic function, neurogenesis and neurotrophic effect together with a direct anti-inflammatory effect [27,28].

The correlation between VAS and index values was less than anticipated. Patients’ perception of overall health by VAS did not correlate well with their perception of improvement in the five dimensions of health (Tables 3 & 4: moderate positive correlation between VAS and index values of the five health dimensions; weak negative correlation between all five health dimensions and VAS). The less than expected correlation between the two components of the Euroqol 5D5L instrument has been documented previously. Group variables, such as ethnicity, culture and university education, have been suggested as possible reasons that may account for this finding [29].

Under one roof, as it were, patients in this study received IORM procedures through an integrated care model not limited in its scope by traditional boundaries of business models, specialisation or the professions. This concept of a patient-centered provision of healthcare is similar to an ‘Integrated Practice Unit’ (IPU) [30]. In this study, operations conformed to regulations for radiation safety, good practice for blood/tissue processing and patient safety. Co-located spaces allowed the following: clinical consultations with equal emphasis on clinical examination including the use of aids such as digital goniometer, weights for strength measurement and imaging review by interventional radiologists; physical therapy advice; separate interventional radiology procedural suite, observation bay and blood/tissue processing under clean air flow. The service described here is different to usual models of care that exhibit inherent constraints, for example, by business models of established procedural suite, where they (4) typically spend two hours at the clinic for the procedure and observation, (5) return in about a week for post-procedure follow-up to check for complications, medication review and written rehabilitation plans, for example, instructions on specific activities such as walking distance, cardiovascular fitness, graded strength training, range of motion exercises, stretching instructions, proprioception training and (6) return for a delayed 3 and 12 month follow-up for clinical assessment and outcome measurement.

There is an increasing recognition that a ‘value-based’ healthcare reimbursement model is the answer to the problem of an increasingly expensive and non-integrated health delivery system [31]. ‘Value’ may be defined as any outcome returned per dollar spent [32]. This requires the measurement of health outcomes in routine clinical practice. This article is the result of such an effort. Our results suggest significant improvement in health outcomes after outpatient IORM procedures in an integrated model of interventional radiology for diseases that would usually require expensive tertiary care with in-hospital bed admission. Considerable cost reductions would be anticipated with our model. However, quality of life years (QALYs) and cost-effectiveness analyses were beyond the scope of this article. Future studies should compare value propositions between outpatient IORM versus in-hospital surgical options. This may allow policy changes that improve health outcomes, reduce medical risks, reduce costs and waiting times and free-up limited resources.

**Conclusion**

This study is a snapshot of a wide spectrum of IORM procedures in a small number of patients over a short period of time. Although the short follow-up allowed capture of outcomes that were chronologically related to a recent procedure, long term follow-up is essential. Future studies using larger patient numbers should address other deficiencies of this article: assess efficacy of individual IORM procedures, correlate condition specific functional outcome scores against QoL health outcomes, long-term follow-up that generates QALYs and the impact of IORM procedures on the use of analgesics including opiates. This retrospective study provides evidence of improved health following IORM procedures in an IPU outpatient model of care under interventional radiology. Notable improvements were in patient mobility, pain and the ability to be more independent. IORM procedures also improved anxiety/depression.

**Acknowledgements and Conflicts of Interest**

I thank the referrers, patients and staff without whom this body of work would not be possible. The project received no funding. I declare that there are no conflicts of interest.
References

Appendix 1

In an integrated service model of interventional orthopaedic and regenerative medicine (IORM), all patients are consulted by a specialist interventional radiologist at pre-procedural evaluation by clinical exam, imaging review - ensuring patients understood their condition, had full information on benefits, limitations and risks of any procedure prior to providing informed consent. Practitioners of IORM procedures incorporate the use of the following: (1) cross speciality principles of disease management in orthopaedic, spinal and neural/neuropathic pain disorders, (2) diagnostic and interventional radiology skill sets, (3) an understanding of donor and target cell & tissue biology, (4) ensure safe onsite blood/tissue processing to prepare therapeutic material that is typically obtained from autologous blood/bone marrow aspirate and adipose tissue, (5) percutaneous ablation techniques and (6) principles of rehabilitation and physical therapy. All patients are routinely followed-up by the radiologist at 10 days, 3 months and 1 year post-IORM procedure.

Appendix 2

Degenerative conditions (Arthritis, Cartilage tears, Tendon tears, intervertebral lumbar disc): Autologous blood derived growth factors from plasma, oxygen ozone gas were used as the therapeutic material.

Neuropathic pain: Radiofrequency ablation of the affected nerve was performed.