Could a disruptive out patient healthcare delivery model reduce escalating in-hospital healthcare costs in knee osteoarthritis

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ABSTRACT

Background Healthcare costs from in-hospital joint surgery for degenerative joint diseases are predicted to significantly increase to potentially unsustainable levels in the next several decades.

Aim As an index model, this paper presents cost-effectiveness predictions for an innovative combination treatment of image-guided percutaneous autologous blood-derived growth factors and exercises (IPGFE) for painful knee osteoarthritis managed in an out of hospital interventional radiology (IR) clinic through a disruptive healthcare delivery model.

Materials and methods Non-randomised retrospective case registry data were analysed. Patients suitable for TKR who underwent IPGFE were included. Knee function outcome scores were converted to quality of life years (QALY) gained. Median percentage improvement after IPGFE in knee function was converted to cost per QALYs by input of direct costs.

Results Median cost per QALY for IPGFE was AU$ 208.33 for 7.2 QALY gained. In comparison, the median cost per QALY for TKR was AU$2739 for 4.5 QALY gained. Incremental cost-effectiveness ratio for IPGFE was AU $4827.77 not spent per QALY gained in comparison to TKR.

Conclusions An out of hospital care model may be a less expensive option to gain better quality of life in comparison to knee joint replacement surgery for some patients. Out of hospital IR techniques should be studied further for their efficacy and potential to offer considerable healthcare cost savings in comparison to joint replacement surgery.

INTRODUCTION

Personal and healthcare economic costs from musculoskeletal conditions are predicted to escalate by 2030.1 Musculoskeletal conditions are the fourth common chronic condition affecting 28% Australians costing AU$ 5.7 billion in 2008–2009 of which AU$1.637 billion was spent on osteoarthritis (OA).2 Forty four per cent of those with arthritis also report cardiovascular disease, back problems and mental health problems.3 In Australia there has been a 47% increase in total knee replacement (TKR) surgery from 2003/2004 to 2012/2013 and a 17% rise in hip replacements during the same period.2 In-hospital joint replacement surgery (JRS) is currently the final treatment option for OA. Aside from dissatisfaction, complications include procedural infection, venous thrombosis, failed prosthesis and implant metal toxicity.4 Around 5–8% undergo complex redo replacements that are more expensive with more risks. The long-term benefits of JRS are unclear.4 Therefore there is a need for an alternative option to reduce escalating costs and risks with at least a similar outcome.

Exercise, cardiovascular fitness, range of motion activities have been shown to be effective in the management of OA.5 The recent emergence of autologous orthobiologics derived from blood, platelets, plasma, bone marrow progenitor cells and fat-derived mesenchymal stem cells has opened up a gamut of percutaneous options for OA.6 Percutaneous interventional radiological (IR) procedures lend well to a minimally invasive approach without an open surgical wound or a foreign metallic implant.

This paper illustrates a prediction cost-effectiveness model when an innovative combination treatment was delivered in
an outpatient setting for patients with knee OA. The method used in patients in this paper is a combination of clinical and imaging correlation for accurate diagnosis. Image-guided percutaneous treatment with autologous blood derived growth factors followed by a tailored graded rehabilitation programme of exercises (IPGFE) in a single point of healthcare delivery model.

MATERIALS AND METHODS
Patients with knee OA, who chose to undergo IPGFE rather than JRS were referred by their general practitioner to an outpatient IR clinic. Preprocedural assessment included a detailed history of presenting complaints, medical, surgical, drug and social history at the IR clinic. Western Ontario and McMaster Universities (WOMAC) knee function scores derived from a web based Knee Osteoarthritis Outcome Score (KOOS) were completed by the patient in isolation, before and after the procedure. Numerical scores were assigned on a Likert scale for pain, stiffness and functional limitations of various activities. A conversion formula \( 100 - \left( \text{raw score} \times 100 / 96 \right) \) was applied to derive the final score.\(^7\) The WOMAC and KOOS scores are widely used and have been validated for functional outcome measure in knee OA.\(^8\) Clinical and radiological imaging correlation for clinical OA and the precise location of treatment was determined by the radiologist. Informed consent was obtained explaining the risks, complications and possible outcomes. Using ultrasound imaging control and 5 cc of 1% lignocaine, autologous blood-derived growth factors were delivered into the relevant knee compartment tissues. The procedure took approximately 60–90 min and patients were discharged home after the procedure. Postprocedure care included a soft knee support while standing and partial weight bearing for 3 days. About 10 days after the procedure, a follow-up consultation by the radiologist ensured there were no complications. Instructions were given on graded rehabilitation, non-provocative activities including muscle strengthening, range of motion activities, proprioception training and cardiovascular fitness. Depending on pain and comfort levels, patients were advised to increase intensity and frequency of activities. A combination of targeted tissue delivery under image guidance, use of autologous growth factors and specific graded rehabilitation as per a proprietary STEMHealth method was used.

Costs and quality adjusted life years (QALY) from TKR surgery were derived from previously published data from an article that used WOMAC function scores to calculate QALY.\(^7\) This was compared to data from this study where QALYs were calculated as the improvement in WOMAC knee function divided over a 10-year period. For example, WOMAC improvement of 50% meant that WOMAC improvement 50% divided by 10 years=5 QALYs. Cost-effectiveness ratio (CER) was calculated as direct costs per QALY gained from IPGFE (AUS\(1500\)). In the previous example, CER would be AUS\(1500/5\) QALYs=AUS \(300\) per QALY gained. Incremental cost-effectiveness was defined as the additional or less QALY gained with additional or less direct cost incurred. Incremental cost-effectiveness ratio (ICER) was calculated as the ratio of the difference between the direct costs of TKR and IPGFE divided by the difference in QALY gained between TKR and IPGFE.

Statistical methods
Cohen’s effect size (d) was calculated by dividing the difference of the mean between the pre and post-WOMAC scores by the SD. p Value was set at <0.01 and a two-tailed t test was used.

RESULTS
Data were available for 23 knees in 20 patients (male: 11, female: 9) with median age of 60 years (range: 40–79 years) who underwent IPGFE. The median age group of TKR patients from previously published data were 66 years (range 45–78 years). There were no complications or hospital admissions post-IPGFE procedure. Median WOMAC pretreatment score of 47.9, (range: 28.22–88.54, SD: 16.7) improved to median post-treatment score of 11.45 (range: –4.1–36.7, SD: 12.09). Median improvement in WOMAC knee function post-IPGFE was 72.4% (range: 39.1–108.2, mean=70.8%) (Cohen’s ‘d’ size of effect=2.09, p<0.01). Follow-up duration of IPGFE patients was 3 months to 12 months (mean 5.6 months).

Direct cost of IPGFE was AUS\(1500\). The median QALY for IPGFE was 7.2 (mean=7.07, range 3.9–10.2, SD=1.7). Cost-effectiveness ratio of IPGFE was AUS\(1500/7.2\)=AUS \(208.33\) per QALY.

Direct cost for TKR in Germany was AUS\(14,535\). The difference in direct costs was AUS\(13,035\) (AU \(14,535–1500\)). Median QALY for TKR was 4.59 (figures 1 and 2). CER for TKR (cost per QALY) was AUS 2739 (1795 Euro/QALY for TKR; conversion of 1 Euro=1.53 AU$, October 2015). Incremental cost-effectiveness ratio between TKR and IPGFE was AUS\((14,535–1500)/(4.59–7.2)=\)less AUS\(4827.77\) in favour of IPGFE (table 1).

DISCUSSION
This paper makes a case for an out of hospital combination treatment option (IPGFE) that may offer a notable cost reduction while at the same time provide a better health outcome in patients suffering painful knee OA who would otherwise be subject to in-hospital TKR. IPGFE was offered via a disruptive healthcare delivery model. The conventional referral pattern of primary care physician to orthopaedic surgery was not adopted. Patient empowerment and informed decision-making led to an out of hospital management option at a single outpatient point of...
The technology of autologous blood-derived growth factors within IPGFE matched an innovative and disruptive interventional radiology business model in healthcare delivery. The radiologist physically examined all patients, reviewed all scans and performed percutaneous treatment on all patients under real-time ultrasound imaging guidance. Patients were followed up and shown rehabilitation exercises by the treating radiologist. This continuum at the point of care healthcare delivery was the core component of IPGFE.

Conventional radiology practice does not involve the one on one direct patient contact delivery of healthcare model described above. Aside from injecting therapeutic substances into knee joints following instructions from other doctors, radiologists do not assume responsibility in the management of patients with OA. The radiologist in this article extended the usual role of ‘injector’ to ‘manager’ of the condition. This role extension within the disruptive model of IPGFE puts patient’s welfare at the centre of healthcare delivery and this paper argues that the ‘disruption’ did deliver cost-effective care to patients.

Arthritis and other musculoskeletal conditions are a major cause of pain and disability. In 2008–2009 healthcare expenditure in Australia totalled AU$ 5.69 billion as the fourth most expensive group (8.9% of total healthcare expenditure) of which 54% or AU$3.091 billion was due to hospital admitted patients. Seventy seven per cent of expenditure for OA occurs in admitted patient hospital services due to the use of joint replacements and arthroscopic surgery. Hence, an out of hospital management option for OA is likely to have a meaningful impact in cost savings in health expenditure.

Although TKR is a well-established procedure, there is a lack of large volume randomised controlled trial evidence comparing outcomes of joint replacement with conservative care for longer than 12 months follow-up post-TKR. Recently the first of its kind randomised controlled trial comparing TKR with conservative management in OA with follow-up out to 1 year showed that there was a significant improvement above baseline function in the conservative non-operated group at 12 months and only 26% of patients in this group crossed over and opted for TKR during the follow-up period. This means that for every 100 patients deemed ready for TKR, there is a possibility that only 26 patients may really require TKR at the end of 12 months following non-surgical treatments. This is a potential reduction of 75% TKRs in patients deemed ready for TKR. There is no randomised controlled trial evidence on the efficacy of TKR in the long term. With current trends, TKR for knee OA is predicted to increase by approximately 673% in the USA between 2007 and 2030. Given the high likelihood of considerable escalation of the number of TKR in the next few decades, the lack of robust long-term data and emerging research data that it is possible that a considerable proportion of patients may not require TKR, it is prudent to evaluate healthcare cost implications of emerging therapies that may offer a suitable alternative, to be allocated research funding in a timely manner. There is no long-term randomised control trial data on the efficacy of autologous blood-derived growth factors. Longevity of IPGFE out to 10 years has been assumed in this model and is a deficiency in the estimations in this article.

Patients in this article suffered 50% reduced function secondary to knee OA. These patients refused TKR and opted for IPGFE. Costs of TKR in Germany were obtained from a paper that also used the WOMAC knee outcome scores as used in patients in this article. The post-treatment follow-up WOMAC score was longer for patients treated with IPGFE (5–6 months) compared to the follow-up WOMAC score post-TKR (3 months). In IPGFE patients,
WOMAC knee function scores improved by 70% from pretreatment baseline with a large statistically significant effect size. The effect size seen in this article is comparable to a systematic review and meta-analysis on studies using blood derived plasma in joint degenerative cartilage disorders.14

The direct costs of IPGFE were compared with direct costs of TKR in Germany.9 Costs of TKR vary across different countries. Direct costs in Australia are higher and range from AU$17 888 to $20 423.15 Applying the estimates from this study, assuming that 25 000 TKR per annum are performed in Australia, a direct cost of AU$ 447.2 million (25 000×AU$ 17 888) would result in 118 750 QALYs gained (25 000 patients×4.59 QALY). If the same patients were to undergo IPGFE the direct costs would amount to AU$37.5 million (25 000×AU$1500) and QALYs gained estimated at 180 000 (25 000×7.2). The estimated additional 61 250 QALYs gained from IPGFE is with a potential cost-savings of AU$ 409.7 million (25 000×AU$1500) and QALYs gained estimated at 180 000 (25 000×7.2). Extrapolating a similar effect for other JRSs, fusion surgeries, the predictions for potential cost savings with better QALYs are potentially staggering.

This paper presents marginal cost-effectiveness and incremental cost-effectiveness ratio as comparison between two distinct interventions to treat knee OA. The potential magnitude of cost savings over-rides several other considerations. This paper does not factor the higher costs from revision TKR, costs incurred from post-TKR complications, costs of drug therapy or cost savings from reduction in pharmacy costs. Additional cost savings by avoidance of low value pre-TKR treatments such as knee arthroscopy were not factored in. As the findings are not in the context of a randomised controlled trial, conclusions on cause and effect or the extent of benefits from IPGFE alone without input from extrinsic factors cannot be assumed. Indirect costs such as those that were incurred outside the clinic eg: cost of pain medications, imaging tests, physiotherapy costs, recent failed arthroscopy surgery, loss of time at work were not assessed. Indirect benefits such as return to work capability and productivity at work were also not assessed.

Savings in healthcare expenditure in OA may lead to efficient allocation of healthcare dollars needed elsewhere. Off loading elective joint replacements to out of hospital healthcare facilities will open up access to other diseases that need in-hospital healthcare. Ultimately, reducing high expenditure in-hospital surgery is likely to impact favourably, by reducing rising insurance premiums across the entire health sector. The economic implications of this paper should serve as an impetus to allocate resources to test this disruptive model of care in a prospective randomised blinded controlled study to assess efficacy and cost-effectiveness. Other options would include a funded central registry for longitudinal data collection with regular long-term follow-up to assess cost-effectiveness and health outcomes.

**Conclusion**

IPGFE as an out of hospital healthcare delivery model is potentially more cost-effective in comparison to in-hospital joint replacement for OA of the knee. IPGFE has to be tested further to assess cost savings, lower risk of medical complications and improved quality of life for patients suffering functional limitation due to knee osteoarthritis. In a climate of escalating healthcare costs, economic downturn and reduced government revenue, the option of IPGFE is a timely opportunity to reduce costs, redirect existing resources and improve access to improved health outcomes.

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