A prospective, randomized, pragmatic, health outcomes trial evaluating the incorporation of hylan G-F 20 into the treatment paradigm for patients with knee osteoarthritis (Part 2 of 2): economic results


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study examined viscosupplementation with hylan G-F 20 for the treatment of osteoarthritis (OA) of the knee in Canada. The comparator was treatment without hylan G-F 20

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population included ambulatory patients over 40 years old in Canada with a primary diagnosis of radiologically verified OA in the study knee (knee most symptomatic or with the most predominant musculoskeletal problem), excluding grade IV.

Setting
The setting was secondary care. The economic study was carried out in Canada.

Dates to which data relate
The date for the effectiveness data was not stated but would appear to have been 1999. Costs were reported in 1999 Canadian dollars.

Source of effectiveness data
The effectiveness data were derived from a single study

Link between effectiveness and cost data
Costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations were not reported. Patients were recruited from 14 sites across Canada (10 rheumatologists and 4 orthopaedic surgeons). A total of 255 patients were recruited, 127 in the intervention group and 128 in the control group. The number of patients excluded was not stated, but the study sample appears to have been appropriate for the research question.
Study design
This was a multi-centre, prospective, cohort study carried out across Canada. The duration of follow-up was 1 year, and there was no loss to follow-up as any missing data were imputed using the hot deck method.

Analysis of effectiveness
The basis for the analysis of the clinical study was intention to treat. The primary health outcome was a patient whose Western Ontario McMaster University Osteoarthritis index (WOMAC) pain score at month 12 was reduced by 20% or more compared to baseline. The secondary outcome was a patient who reduced their pain by 20% or more, and also reduced either their stiffness or their physical functioning score by 20% or more. The instrument used was the WOMAC Likert 3.0 which is a disease specific quality of life instrument that asks the patient questions concerning the study knee. The two groups were comparable at baseline.

Effectiveness results
The percentage of patients improved using the primary definition was 69% in the intervention group compared to 40% in the control group, (p=0.0001).

The percentage of patients improved using the secondary definition was 62% in the intervention group compared to 35% in the control group, (p=0.0001).

Clinical conclusions
Both increments were statistically significant and exceeded the clinically important difference of 20% established a priori as part of the research design.

Measure of benefits used in the economic analysis
Quality-Adjusted Life Years (QALYs) were used to measure benefit in the economic analysis. QALYs were calculated using the HUI3 health status instrument, which measures 8 attributes: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain/discomfort. This provides an overall utility score where dead = 0 and perfect health = 1.

Direct costs
Discounting was not relevant as costs were incurred over a period of one year. A comprehensive societal perspective was adopted as the primary perspective of the analysis. Hospital costs included outpatient resources, inpatient costs, and medication. Patient costs included travel, devices, medication, and dispensing fees. Other costs were for private plans which included medication. Costs were based on actual data and were reported in 1999 Canadian dollars.

Statistical analysis of costs
Costs were treated deterministically.

Indirect Costs
Discounting was not relevant as costs were incurred over a period of one year. The indirect costs included were time lost from work and time lost from usual activity. Patient lost productivity was valued at the Canadian average industrial wage rate for both work and non-work time losses. Costs were reported in 1999 Canadian dollars.

Currency
Canadian dollars (Can$).

Sensitivity analysis
The authors carried out sensitivity analysis to explore the impact of uncertainty in the parameter values. One-way sensitivity analysis was used to explore effectiveness high, effectiveness low, costs high, costs low, and alternative definition of lost time.

**Estimated benefits used in the economic analysis**
The improvement in mean utility was 0.13 in the intervention group compared to 0.03 in the control group, (p<0.0001).

Patients in the intervention group gained 0.071 QALYs (95% CI: 0.017 - 0.126).

**Cost results**
The average cost of treatment in the intervention group was Can$2,124 (SD: Can$2,528).

The average cost of treatment in the control group was Can$1,415 (SD: Can$2,033).

The mean difference in costs was Can$710 (95% CI: Can$147 - Can$1,273)

**Synthesis of costs and benefits**
Benefits and costs were combined to estimate a cost per QALY. The cost per QALY gained was Can$10,000.

**Authors’ conclusions**
The author concluded that hylan G-F 20, when used in conjunction with appropriate care, provided an improvement in outcomes that was both clinically important and statistically significant. Total costs were higher when hylan G-F 20 was selected as a treatment option but the cost per QALY gained was well below the suggested Canadian threshold.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of comparator was clear. The ‘world without Hylan G-F 20’ option was selected, as the aim of the study was to establish how effective Hylan G-F 20 was in the real world. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness was based on a prospective cohort analysis which appears appropriate for the study question. The authors acknowledged that, as the study was open-labelled, there may have been some bias in favour of hylan G-F 20 treatment that could have affected the outcomes. Study groups were comparable at baseline and, although study samples were large, no power calculations were reported.

**Validity of estimate of measure of benefit**
Economic benefit was measured by QALYs, which were estimated using the HUI3 preference-weighted health status instrument.

**Validity of estimate of costs**
The analysis of costs was conducted from a societal perspective and, given this perspective, it appears that all relevant direct and indirect costs were included in the analysis. Unit costs and quantities of resources were not reported separately in the analysis, although analysis of items such as medications, hospitalisations, time loss from work, etc, was reported. A sensitivity analysis was conducted and the source of cost and resource consumption was appropriately reported.
Other issues
The authors made appropriate comparisons of their findings with those from other studies, and the issue of the generalisability of the study results to other settings was also discussed; the authors saying that, although the results were not directly applicable to other countries, they felt that, in general, the clinical findings would be fairly generalisable. Sensitivity analysis was conducted which gave similar results to the base result and therefore helps to validate the results of the study.

Implications of the study
The authors did not make any recommendations for policy or practice.

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