

Dynamic intraligamentary stabilisation for the treatment of the anterior cruciate ligament rupture: A health technology assessment for Switzerland

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ABSTRACT

Background: In addition to current standard therapies (primary operative ACL reconstruction [pOP], primary conservative treatment with possible delayed ACL repair [pKONS]), a new therapeutic option (dynamic intraligamentary stabilisation [DIS]) has emerged.

Objectives: To assess patient benefits and costs of DIS compared to standard therapies (pOP, pKONS) in Switzerland.

Methods: A decision tree was developed to analyse cost-effectiveness over two time horizons (2 and 15 years). We performed a literature search for effectiveness and safety outcomes in electronic databases. Effectiveness data were pooled with meta-analysis, where suitable. Direct medical costs and productivity losses were calculated in Swiss Francs (year 2012) using clinical expert information and administrative databases.

Results: DIS showed to be at least as effective as the comparators. The ratio of patients at 2 years with equivalent sports level as pre-injury was 49% (95%-CI: 36%-66%) for DIS, 39% (18%-82%) for pOP and 36% (26%-51%) for pKONS. The frequency of safety events was similar for the three strategies. Total costs at 2 years were 21'700 CHF for DIS, 26'000 CHF for pOP and 17'000 CHF for pKONS. Sensitivity analyses did not lead to significantly different conclusions.

Conclusions: DIS has the potential to be a valuable treatment option for ACL rupture. However, data is scarce and studies with rigorous design and longer follow-up should be performed.

METHODS

We performed an update-literature search in electronic databases (Pubmed; Cochrane Library) of a previously performed HTA (Gesundheitsdirektion Zürich, 2009) on therapy for ACL-rupture. In addition we used unpublished DIS-data as well as guidelines. We included systematic reviews of cohort studies and RCTs (for pOP; pKONS; DIS) and observational case series for DIS of patients with acute ACL rupture. Functional outcome (e.g. scores) had to be reported, as well as safety outcome. References were assessed according to pre-specified inclusion criteria and data extracted. Effectiveness data were pooled with meta-analysis, where suitable.

A decision tree was developed to analyse cost-effectiveness. We compared integral therapy strategies assigning all downstream interventions to the primarily intended strategy. For example, if pKONS patients were treated with delayed ACL-reconstructions, these interventions were included in the pKONS strategy (see Figure 1).

Direct medical costs of current Swiss clinical procedures were calculated in 2012 Swiss Francs using clinical expert information and administrative databases (e.g. SwissDRG). Productivity losses were calculated with the human capital approach. We used a payer as well as a societal perspective and applied sensitivity analyses. The time horizon was 2 and 15 years. QALYs could not be calculated due to lack of empirical utility data.

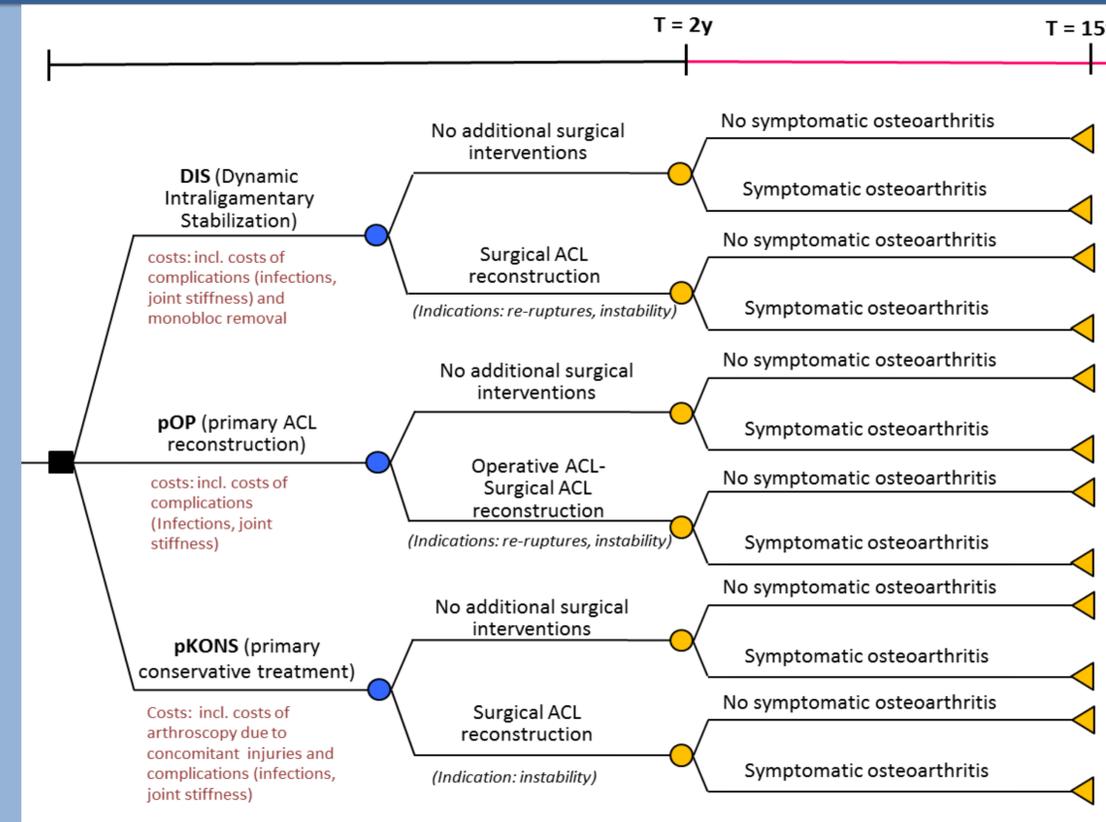


Figure 1: Decision tree for modeling the occurrence of medical conditions, patients benefit and costs. The structure of the decision tree is not directly linked to “clinical decision making” of physicians. It does not represent a treatment pathway as known and shown in clinical guidelines. This decision tree serves the health-economic modeling of medical conditions and cost for the treatments.

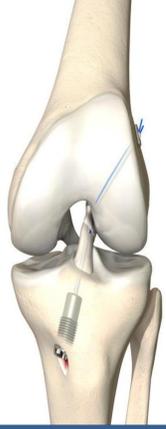
RESULTS

We were able to include five DIS case series with 415 patients, two systematic reviews of cohort studies of the comparators and one RCT with a head-to-head comparison of pOP and pKONS. Patient characteristics in the DIS studies were similar to those in pOP and pKONS studies.

DIS showed to be at least as effective as the comparators. For example the ratio of patients at 2 years with equivalent sports level as pre-injury, measured with Tegner-Score, was 49% (95%-CI: 36%-66%) for DIS, 39% (18%-82%) for pOP and 36% (26%-51%) for pKONS (see Figure 2).

The frequency of safety events (such as infections or joint stiffness) was similar for the three strategies. The rate of treatment failure (due to re-rupture or instability) was similar for DIS and pOP but higher for pKONS (due to instability requiring delayed reconstruction).

Total costs (direct medical costs plus productivity losses) at 2 years were 21'700 CHF for DIS, 26'000 CHF for pOP and 17'000 CHF for pKONS. The difference in costs between pOP and DIS was due to lower productivity losses for DIS. The difference in costs between pKONS and DIS was mainly due to lower direct medical costs for pKONS (see Table 1).



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RESULTS CONTINUED

At 15 years, the expected probability to be free of symptomatic knee osteoarthritis in the operated knee was approximately 90% for all strategies. Again, the ranking of total costs at 15 years was the same as at 2 years. Sensitivity analyses did not lead to significantly different conclusions.

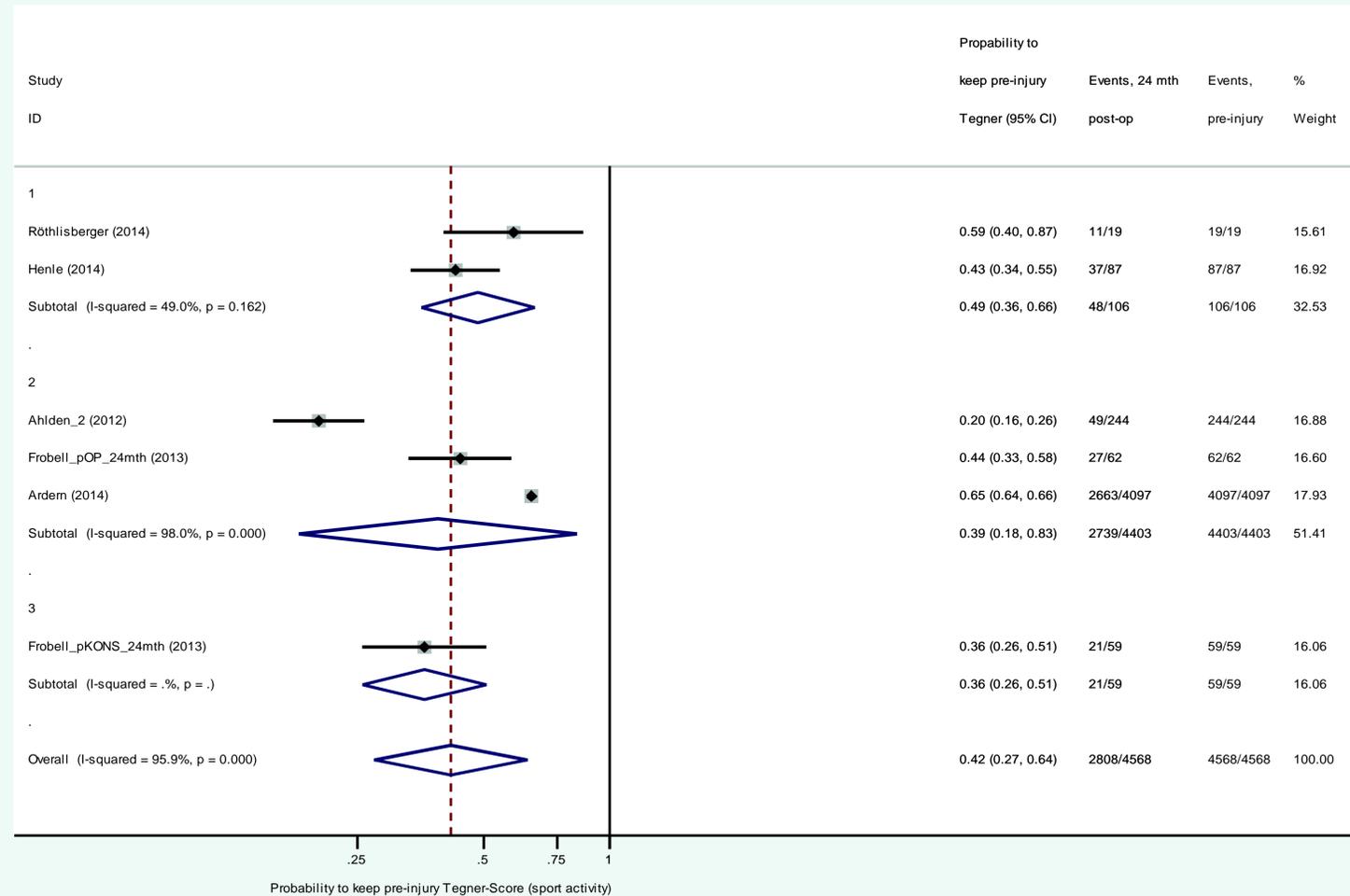


Figure 2: **Probability to achieve the same activity level as prior to injury.** Results for DIS (1), pOP (2) and pKONS (3) are shown as probability after 2 years of achieving at least the same activity level as prior to injury (measured with Tegner-Score), (risk ratio; 95%-confidence interval).

	DIS	pOP	pKONS
0-2 years			
Outcome:			
Probability for same Tegner Score as pre-injury	0.49	0.39	0.36
Changes of Tegner Score	0.02	-1.63	-3.68
Costs:			
Direct costs	12'842	12'675	7'812
Indirect costs	8'850	13'367	9'168
Total costs	21'692	26'042	16'980
0-15 years	Scenario 1	Scenario 2	
Outcome:			
Probability not suffering symptomatic osteoarthritis after 15 years	0.904	0.910	0.905
costs:			
Direct medical costs	14'942	14'447	14'757
Indirect costs	10'387	10'027	14'892
Total costs	25'329	24'474	29'650

Table 1: **Direct medical costs, loss of productivity and total costs for the 3 therapeutic strategies.** Time horizon: 0-2 years and 0-15 years. For DIS two different scenarios were assumed to suffer a symptomatic osteoarthritis after 15 years (scenario 1 und scenario 2).

CONCLUSIONS

According to the data available, DIS seems to be a valuable option for treatment of ACL rupture in Switzerland. However, the data base is small and has to be strengthened with studies of rigorous design to evaluate comparative effectiveness (e.g. an RCT with head to head comparison of DIS versus the comparators) and longer follow-up data of treated patients to evaluate safety aspects (e.g. in a compulsory clinical register).

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