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Development of a national knee ligament registry

- Summary

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In 2004 the world's first national knee ligament registry (NKLR) was started in Norway. This thesis describes the background, design, implementation and the first results from this registry.

Furthermore it outlines how a registry can be used to develop clinically relevant guidelines on timing of primary ACL reconstruction, and comparisons are done between the NKLR and similar registries in Denmark, Sweden, and the USA (MOON).

It is the main intention of the registries to contribute to quality control and improvement of the surgical cruciate ligament procedures. This may be done through establishing evidence based national guidelines and protocols for surgical procedures and rehabilitation. The NKLR has calculated that if 14 patients—registered in the database—with one specific fixation device show failure, this may be considered a failure of that specific device. This will enable the NKLR to give early warnings on poor procedures and devices, and to identify prognostic factors.

The NKLR provides information for the orthopedic community at regular intervals on the outcomes of surgical treatment of the cruciate ligaments with different methods. The hard endpoints are clear and unequivocal, i.e. revision reconstruction and total knee replacement. Causality of failure may not be sufficiently and accurately documented in the NKLR, but it will provide information as to where there may be potential problems and direct future analysis and studies toward these areas. The inclusion of soft endpoints – the KOOS which assesses the patients' opinion about their knee and associated problems – are essential to make a complete assessment of the benefits of an intervention. In addition follow-ups with the KOOS will enable the NKLR to monitor the long term outcomes of a treatment on a specific condition in an entire population. Since the NKLR will provide real-time information and can thus be analyzed on an ongoing basis, they have the potential to reveal problems long before they would be reported by traditional methods (e.g. RCTs). This will undoubtedly benefit all interested parties, not least the patients.

The NKLR has found that the annual population incidence of primary ACL reconstructions was 34 per 100,000 citizens, while the incidence in the 16 to 39 years age group was 85 per 100,000 citizens. These figures from the NKLR are reliable due to a compliance of more than 95%. Since the ratio of surgically treated versus conservatively treated cases has not been sufficiently studied, the population incidence of ACL injuries is not known.

The NKLR have provided physicians and physiotherapist with a tool to estimate the individualized risk profiles for cartilage lesions and meniscal tears based on the logistic regression model. In general the NKLR, based on this tool, found that concludes that the odds for a cartilage lesion in the adult knee (i.e. 17 years and older) increased by nearly 1% for each month that elapsed from the injury date until the surgery date, and the presence of cartilage lesions was associated with a nearly two-fold increase in the risk of having meniscal tears, and vice versa, independent of patient age. These calculations suggest that early surgery is associated with fewer meniscal tears and cartilage injuries.

Comparisons of the Scandinavian national ACL registries (i.e. NKLR and similar registries in Denmark and Sweden) reveal only minor differences. Some of the differences are beneficial since they will enable the registries to conclude on the most efficient surgical protocol (e.g. on the use of prophylactic anticoagulation). The similarities are an advantage since they will enable the registries

to pool of data and therefore, earlier than a single registry could or even at all, conclude on the outcome of rare cases. Thus the Scandinavian ACL registries will generate new data about ACL reconstructions and they will contribute to a better understanding of ACL epidemiology. They will be the only source of data on performance of a wide range of different implants and techniques. They will also influence the selection of methods for ACL reconstructions in Scandinavia and hopefully in other countries in the future.

A comparison of the MOON cohort in the USA and the NKLR reveals several discrepancies, amongst others in completeness of registered data; limitations in geographically coverage and generalizability of raw data to national data; procedural preferences; organization of the healthcare system, necessity of insurance and easy access to providers. All these differences make comparisons complicated, and render a generalization from Norwegian to American conditions impossible.

Thus the NKLR have the capacity to define the epidemiology of cruciate ligament surgery, to serve as an early warning system for premature device and procedure failure, and to identify factors that are associated with both good and poor outcomes. On the basis of this evidence, clinical practice can be improved following the best example through feedback to hospitals and surgeons.