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ORIGINAL STUDY

Protocol and descriptive epidemiology of the SIGASCOT Italian multicentric registry of revision ACL reconstruction: a 1-year pilot study

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The aim of the present study was to present the demographic and baseline results of the first year of course of the SIGASCOT Italian registry of Revision ACL reconstruction.The data of the patients undergoing revision ACL reconstruction, enrolled in by 20 SIGASCOT members from March 2015 to May 2016, were extracted from the Surgical Outcome System (SOS).

Overall, 126 patients were enrolled; 18 were excluded due to incomplete data. Mean age at surgery was 30.4 ± 9.3 years (median 29; 23-38), mean BMI was 22.6 ± 2.3 kg/m2 and 77% were males. Revision was performed with a single-bundle technique in 94%, using allograft in 57% of cases and autograft in 43%. Only 28% had both menisci intact, and meniscal repair or replacement was performed in 25% of patients for medial meniscus and 8% for lateral meniscus. During the first year of enrollment, the SIGASCOT Italian ACL revision registry was able to collect the data of more than 100 patients. The revision ACL reconstruction was usually performed with a single-bundle technique, using allograft and autograft almost in the same extent

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Since this is a multicentric study of a network of orthopaedic surgeons, all have been listed as authors. According to journal preferences, some authors could be listed under the definition of "SIGASCOT ACL Revision Team".

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INTRODUCTION

The value of registries in the orthopaedic practice and in the knowledge of outcomes is becoming increasingly evident *(11,12,22-24,30)*. This is true especially for those uncommon procedures that would require years and years of practice to collect an adequate single-centre case series to allow the analysis of outcome predictors and failure risk factors.

Revision Anterior Cruciate Ligament (ACL) reconstruction is one of these cases; differently from primary ACL reconstruction, the literature is scarce of case series evaluating revision procedures. The few systematic reviews available reported the pooled outcomes of 863 to 1090 patients *(9,31)*, however without a deep analysis of the effect on the clinical outcomes of variables such as sex, age, graft, meniscal and cartilage status, because of the high heterogeneity within each study.

Differently, registries have been reported to be able to collect large cohort of patients, providing important insights regarding the outcomes of the revision ACL reconstruction, in particular regarding the graft effect *(18)*, the comparison with primary procedure *(13)*, the effect of the surgical technique *(26)* or the meniscal and cartilage injury *(3,19,27)*.

Currently, four registries have been established to collect the data and the outcomes of revision ACL reconstruction, under the initiative of both National Health Systems and National Scientific Society: the Danish Knee Reconstruction Registry (DKRR) *(13,14)*, the Norwegian Knee Ligament Registry (NKLR) *(5)*, the Mutlicenter ACL Revision Study (MARS) created with the support of the American Orthopaedic Society for Sports Medicine (AOSSM) *(3,18-20)* and the cohort of the Societè Francaise d'Arthroscopie (SFA) *(26,27)*. The comparison of such registries showed significant differences among them regarding graft choice and intra-articular pathologies, thus suggesting a particular caution for the clinicians when applying findings from one cohort to their own population *(16)*.

In Italy, the widest scientific society that assemble more than 850 practitioners of Orthopaedic Surgery and Sports Traumatology is represented by the Italian Society of Knee, Arthroscopy, Sport, Cartilage and Orthopaedic Technologies (SIGASCOT) *(8, 8,29)*.

The aim of the present study was therefore to introduce the SIGASCOT Italian Registry of Revision ACL Reconstruction, to present the baseline demographic and clinical data collected in the first year, and to compare them with the other available National Revision ACL Registries.

The hypothesis was that during the first year it was possible to collect at least 100 cases, and that baseline demographic and clinical outcomes were different from the other registries.

MATERIALS AND METHODS

Study Design

Under the initiative of the Italian Society of Knee Surgery, Arthroscopy, Sports Traumatology and Orthopaedic Technologies (SIGASCOT), a multicentric prospective longitudinal cohort study aimed to collect the epidemiology and the outcomes of revision ACL reconstruction in Italy was developed.

For this purpose, after a Society Board meeting, 20 members form 19 centres were chosen according to the experience in ACL reconstruction and invited to participate in the study. During the whole 2015, the selected members were asked to participate in a training to receive the instruction regarding the study design and to learn the data collection methods. The members were also encouraged to set periodic meeting within the principal National Congresses in order to review data collection methods and improve cohesion among the group members.

Participants

The members included in the study group were asked to enrol all the patients scheduled for revision ACL reconstruction within their own centre. Inclusion criteria for patients enrolled in the study included all patients with ACL deficiency evaluated at the clinic and identified as having experienced failure of their ACL reconstruction, as defined by the surgeon by either MRI, knee laxity (5 mm side-to-side difference on arthrometer testing), a positive pivot shift or Lachman test, functional instability,

and/or by arthroscopic confirmation *(20)*. Patients with concomitant injuries to the medial and lateral collateral ligaments, posterior cruciate ligament, or posterolateral complex were also included. Patients unwilling or unable to complete their repeated questionnaire after their initial visit were excluded.

Treatment

The surgical technique for revision ACL reconstruction was left to the complete discretion of the operating surgeon, as well as the graft choice. Both allograft and autograft were allowed, either from ipsialateral and contralateral limb. Combined procedures such as meniscectomies, cartilage procedures, osteotomies, other ligaments repair or reconstruction and meniscal replacement were allowed and performed according to each surgeon preference based on personal indications.

Also post-operative indications, rehabilitation and return to sport were left to complete discretion of the operating surgeon based on personal preferences, surgical technique and concomitant procedures performed.

Data Collection

For this purpose, the Surgical Outcome System (SOS, Arthrex Inc, Naples, Florida, USA) was used to collect the data. The Surgical Outcome System is a web platform protected by a user-specific password, which allows the storage of the patient's details and outcomes in an anonymous form.

The system contemplates a surgeon-based part that includes basic demographic details, previous surgeries, intraoperative findings and surgical details. Specifically, age, sex, race, BMI, side, smoking habits, diabetes, previous ligament and meniscal procedure (partial\subtotal meniscectomy or repair), surgical technique for revision ACL reconstruction, graft used, meniscal lesions, condropathy according to Outerbridge classification, meniscal procedures (none, partial\subtotal meniscetomy, repair, substitution), concomitant surgeries (ligament or osteotomy) were collected.

The patient-based part of the system contemplate a series of questionnaires, including the Visual Analog Scale (VAS) for pain, the Knee injury and Osteoarthritis Outcome (KOOS) score and the Veteran Rand 12 item health survey (VR-12), administrated according to the following protocol:

- Baseline: VAS, KOOS, VR-12
- 2 weeks: VAS
- 6 weeks: VAS
- 3 months: VAS, KOOS
- 6 months: VAS, KOOS, VR-12
- 12 months: VAS, KOOS, VR-12
- 24 months: VAS, KOOS, VR-12

After giving informed consent, patient's e-mail were collected and inserted in the system along with demographic information. Than the system provided to send an electronic link to the patient to fill an online questionnaire with the selected scores contemplated by each follow-up evaluation. Reminders were sent in case of lack of response within a predetermined time frame based on the follow-up visit.

The involved members were also encouraged to report physical examination and collect radiographic and MRI imaging, despite not systematically required by the SOS.

Statistical Design

A Microsoft Excel sheet with the study database (including demographic data, surgical details and outcomes) was generated directly from the SOS website.

Continuous variables were reported as mean ± standard deviation, while categorical variables were reported as absolute number and the percentage over the total. Median and interquartile range was also calculated for the age at surgery and for baseline values in order to allow comparison with the other registries. In case of missing data, the parameter was analysed based on the available data, reporting the total number of patients evaluated for each variable.

A chi-square test was used to compare the categorical variables such as sex, graft, meniscal injuries and cartilage injury with the same variables of the other registries from Magnussen et al. (MARS, NKLR, SFA) *(16)* and Lind et al. (DKRR) *(13)*. Statistical siginificance was considered with $p < 0.05$.

RESULTS

Overall, 126 patients were enrolled in the study and inserted in the SOS from March 2015 to April 2016. However, 18 patients were excluded from the present analysis due to inadequate completion of baseline evaluation and lack of clinical outcomes. Therefore, 108 patients were analysed.

Patient's characteristics

The mean age at surgery, available for 106 patients, was 30.4 ± 9.3 years (median 29; 23-38), with most of the patients (39%) comprised between 25-35 years. Male sex was predominant (77%), and the mean BMI was 22.6 ± 2.3 kg/m2, with only 11% overweight (< 25 kg/m2). Right knee was involved in 65% of cases and left in 35%. Most of patients were not smokers and none had diabetes (table I). Apart from previous ACL reconstruction, 33% and 3% had a previous procedure involving medial or lateral meniscus respectively, mostly partial meniscectomy (table II).

Surgical details

Revision ACL reconstruction was performed in 94% of cases with a single-bundle technique. Autologous or allogenic bone graft was used in 8% and 17% of cases respectively. Tendon allografts, mostly Achilles tendon and BPTB were used in 57% of cases, while autograft in the remaining 43% of cases. In 3% of cases, a contralateral graft was harvested (table III). When reported, the mean diameter of the graft was 8.9 ± 1.0 mm.

Excluding meniscectomies, an isolate revision ACL reconstruction was performed in 74% of cases.

Meniscus and cartilage status

In the 90 cases where meniscal status was reported, a medial or lateral meniscal lesion was present in 31% and 34% of cases respectively. Based on the lesions and previous meniscectomies, the medial or lateral meniscus was reported to be intact in 44% and 58% of cases respectively. Both menisci were intact in only 28% patients, while injury or defect of both menisci were reported for 15% of cases (table II).

Table I. — Demographic details of the patients included in the registry

Age at surgery (years)	(n=106)
Mean	30.4 ± 9.3
<18	8 (8%)
18-25	26 (25%)
25-35	41 (39%)
>35	31 (29%)
Sex	(n=106)
Males	82 (77%)
Females	24 (23%)
BMI (kg/m2)	(n=65)
Mean	22.6 ± 2.3
<20	4 (6%)
20-25	54 (83%)
>25	7 (11%)
Smoker	(n=86)
Yes	15 (17%)
No	71 (83%)
Diabete (Yes/No)	(n=91)
Yes	0 (0%)
No	91 (100%)
Side (R/L)	(n=98)
Right	64 (65%)
Left	34 (35%)

A medial meniscectomy or medial meniscus repair\substitution were performed in 12% and 25% of cases respectively, while a lateral meniscectomy or lateral meniscus repair\substitution were performed in 12% and 8% of cases, respectively (table II).

In the 90 cases where cartilage status was reported, condropathy was present in 31%, 12% and 2% of cases for medial, lateral and patellofemoral compartment, respectively (table IV, figure 1).

Clinical scores

Of the 126 enrolled patients, 101 patients (80%) completed the pre-operative VAS for pain score, reporting a mean value of 3.3 ± 2.7 points. Eighty-three (66%) completed the pre-operative KOOS scores (table V); the lower values of the KOOS scores were reported for the Qol and Sport

Table II. — Previous meniscal procedures, intra-operative new lesions and treatments performed

Medial meniscus			
Intraoperative finding		Operative procedure	
Previous partial meniscectomy	13 (14%)	Partial meniscectomy	8 (9%)
Previous subtotal meniscectomy	11 (12%)	Subtotal meniscectomy	3 (3%)
Previous repair	6 (7%)	Repair	12 (13%)
Lesion	28 (31%)	MAT\Scaffold	11 (12%)
Intact	47 (52%)	No treatment	0 (0%)
Lateral meniscus			
Intraoperative finding		Operative procedure	
Previous partial meniscectomy	2 (2%)	Partial meniscectomy	10 (11%)
Previous subtotal meniscectomy	0 (0%)	Subtotal meniscectomy	1 (1%)
Previous repair	1 (1%)	Repair	7 (8%)
Lesion	31 (34%)	MAT\Scaffold	0 (0%)
Intact	53 (58%)	No treatment	15 (17%)

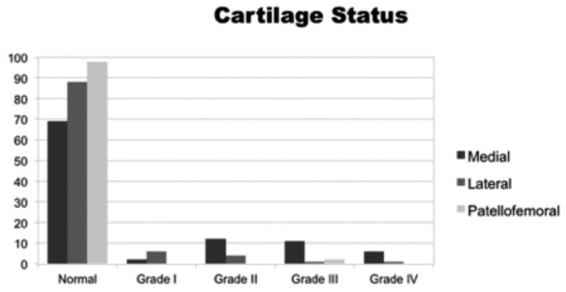

Fig. 1. — Graphic distribution of chondral lesions according to compartment involvement and grade of severity

subscales. Eighty-six (68%) completed the pre-operative VR-12 score, reporting a mean value of 50.8 ± 11.1 and 42.7 ± 10.2 for the Mental and Physical sub-scales respectively.

Comparison with MARS, NKLR, DKRR and SFA registries

According to the data reported by Magnussen et al. *(16)* and Lind et al. *(13)* a statistical comparison was possible for the categorical variables sex, graft, meniscal and cartilage injury. A significant higher number of male patients were reported compared to the MARS, NKLR and DKRR registries. Regarding graft choice, no differences were reported compared to the MARS. More frequent use of HS autograft and less use of allograft was proper of the NKLR, DKRR and SFA registries. Incidence of medial and lateral meniscus injury resulted similar to the MARS and NKLR registries, while the incidence of medial and lateral compartment cartilage injury was similar only to the NKLR registry. Patellofemoral articular cartilage injury resulted lower compared to all the three registries (table VI).

A comparison of baseline values of all the KOOS subscales was possible with 460 patients of the MARS reported by MARS Group et al. *(20)*, however statistical comparison was not possible due to the lack of data (table V).

DISCUSSION

The most important finding of the present study was that, through the institution of the Italian SIGASCOT registry, it was possible to prospectively collect more than 100 ACL revision procedures within the first year. Moreover, significant differences were found compared to the populations followed in revision cohorts in Norway, France and North America, confirming the caution when applying the findings of a registry to a different population.

The number of patients enrolled in the first year of the present registry by the 20 members represents

Table III. — Details of surgical technique and graft choice

Technique	(n=108)
Single Bundle	102 (94%)
Double Bundle	6 (6%)
Concomitant procedures	(n=108)
Isolate	80 (74%)
Lateral Plasty	10 (9%)
PLC reconstruction	2 (2%)
MCL repair	5 (5%)
MAT\Scaffold	11 (10%)
Graft	(n=89)
Autograft	
BPTB	24 (27%)
Ipsilateral	22
Contralateral	2
HS	12 (13%)
Ipsilateral	11
Contralateral	1
QT	2 (2%)
Ipsilateral	2
Contralateral	0
Total Autograft	38 (43%)
Allograft	
Achilles	33 (37%)
BPTB Allograft	10 (11%)
TA Allograft	2 (2%)
TP Allograft	3 (3%)
HS Allograft	3 (3%)
Total Allograft	51 (57%)
Graft diameter	(n=59)
Mean	8.9± 1.0
Bone Grafting	(n=108)
Autograft	8 (8%)
Allograft	17 (17%)

an encouraging result. The MARS presented the baseline data of 460 enrolled in the first 3 years by 87 members *(20)*, the DKRR reported the pre-operative scores of 222 out of the 443 revisions enrolled in almost 2 years *(14)*, while the NKLR had only 28 revisions in the first 2 years *(5)*.

The population undergoing revision ACL reconstruction in Italy does not substantially differs from those of North America, Denmark, Norway and France, as all populations present an higher involvement of male patients, a median age at surgery in the late twenties (26 to 29) and normal or minimally overweight BMI. However, a significantly higher number of male patients were reported in the Italian population compared to North America, Denmark and Norway. This could be probably due to the massive involvement of young females in the practice of pivoting sports such as soccer and handball, proper of North American and Scandinavian culture *(2,6,15,21)*.

Regarding intra-articular condition and findings, several differences were reported. A lower incidence of chondral lesions was present compared to the patients of the MARS registry. This could be due to an almost 4-points higher BMI of the North American population, that could have been responsible of increased chondral damage *(1)*. Despite statistical comparison of BMI was not possible, the lower value of Italian population could be the reason of the fewer damages reported in such patients respect to the other populations.

Interesting considerations could be obtained by the analysis of meniscal defect, lesions and management. First of all it is noteworthy how in the present registry only 28% of patients had both intact menisci, while 15% had both injured menisci. This confirms the trend of the frequent meniscal involvement in the patients undergoing revision procedure. In a report by the SFA *(27)* it was in fact reported a progressive meniscal damage, from 23% during primary reconstruction to 37% between primary reconstruction and revision, and even 67% during the revision procedure. This does not substantially differs from what reported in the Italian revision population, where a previous medial or lateral meniscectomy described in 33% and 3% of cases respectively, summed to the 31% and 34% of new medial or lateral meniscal lesion respectively, resulted in a total of 56% and 42% involvement of medial and lateral meniscus, respectively. This issue could subtend important clinical implications, as meniscal status in the revision setting has been demonstrated to influence objective IKDC and knee laxity *(27)*. If we consider also the higher incidence of knee osteoarthritis

Table IV. — Cartilage lesions classified as anatomical location and grade of severity

	MFC	MTP	LFC	LTP	PF
Normal	64 (71%)	74 (82%)	74 (82%)	86 (96%)	88 (98%)
Grade I	2 (2%)	3 (3%)	3 (3%)	2 (2%)	0 (0%)
Grade II	10 (11%)	5 (6%)	5 (6%)	1 (1%)	0 (0%)
Grade III	9 (10%)	5 (6%)	5 (6%)	1 (1%)	2 (2%)
Grade IV	5 (6%)	3 (3%)	3 (3%)	0 (0%)	0 (0%)

Tabel V. — Comparison of baseline KOOS score between the SIGASCOT Italian registry and the North American MARS registry [17]

Score	Scale	MARS (n=460)	SIGASCOT (n=82)
KOOS	0-100		
Symptoms		68 (54-82)	68 (54-75)
Pain		75 (61-86)	78 (58-92)
ADLs		87 (71-96)	87 (65-96)
Sport/Rec		45 (25-65)	40 (25-60)
Qol		31 (19-44)	38 (25-50)
WOMAC	0-100		
Stiffness		75 (50-88)	75 (63-100)
Pain		85 (70-95)	85 (70-95)
ADL		87 (71-96)	87 (65-96)

after revision ACL reconstruction, estimated around 60% *(10)* and the double compared to primary reconstruction *(7)*, repair of meniscal lesions should be always attempted especially during revision surgery. Meniscal repair was in fact reported in around 30% of the medial meniscus lesion in the MARS registry, and in 10% to 20% in the NKLR and SFA registries as well *(16)*. In the Italian SIGASCOT registry, a similar or even more evident approach was noted, since meniscal repair or even replacement with an allograft was reported in more than 1 out of 4 patients. This could be due to several reasons: first, the present registry involves patients enrolled in the most recent years (from 2015 to 2016) where meniscus-saving procedures (especially those involving meniscal substitution with allograft or scaffolds) are more settled in clinical practice respect to the 1994-2006 period of the SFA registry, the 2004-2011 period of NKLR and the 2006-2011 period of MARS16. Second, the surgeon members of the SIGASCOT society (similarly to the AOSSM in the context of MARS registry) could represent a super-selected group of clinician that tends to apply the most recent and up-to-date approaches compared to the general national orthopaedic population.

Regarding graft choice, the approach to use both autograft and allograft in similar proportions was common between the Italian and North American registries *(16)*. Due to the marked use of allogenic tissue, the use of alternative graft sources such as contralateral graft or quadriceps tendon resulted limited (3% and 2% respectively). Conversely, a higher use of HS autograft (probably harvested from contralateral uninjured leg) and a lower use of allograft was reported in the Scandinavian and French registries *(16)*. This could be due, despite surgeon's personal preferences, also to cultural, commercial, legal and regulatory issues *(4)*.

Finally, despite a non-statistical comparison,

Table VI .— Statistical comparisons between the various variables of the MARS, NKLR, SFA [18] and DKRR [10] registries

	MARS	NKLR	DKRR	SFA	SIGASCOT	vs MARS	vs NKLR	vs DKRR	vs SFA
	(n=1216)	(n=793)	(n=1099)	(n=277)	(n=108)				
Age (years)	26 (20-34)	28 (21-37)	NA	27 (23-32)	29 (23.38)	NA	NA	NA	NA
Sex (% males)	58%	56%	54%	69%	77%	P=0.0002*	P=0.0001*	P<0.0001*	P=0.1519
BMI (kg\m2)	26.1±4.6	24.9±4.2	NA	23.5±3.3	22.6±2.3	NA	NA	NA	NA
Graft choice									
BPTB autograft	318 (26%)	257 (32%)	308 (28%)	155 (56%)	24 (27%)	P=0.7714	P=1544	P=0.9135	P<0.0001*
HS autograft	245 (20%)	444 (56%)	462 (42%)	107 (39%)	12 (13%)	P=0.1416	P<0.0001*	P<0.0001*	P<0.0001*
QT autograft	19 (2%)	13 (2%)	NA	6 (2%)	2 (2%)	P=0.6949	P=0.6897	NA	P=0.6634
Allograft	601 (49%)	30 (4%)	231 (21%)	0 (0%)	51 (57%)	P=0.7960	P<0.0001*	P<0.0001*	P<0.0001*
Medial meniscus injury	551 (45%)	188 (24%)	NA	155 (56%)	28 (31%)	P=0.9126	P=0.1835	NA	P=0.0001*
Lateral meniscus injury	444 (36%)	119 (25%)	NA	56 (20%)	31 (34%)	P=0.7888	P=0.0855	NA	P=0.0099*
Medial articular cartilage injury	590 (48%)	268 (34%)	NA	136 (49%)	28 (31%)	P=0.0026*	P=0.2282	NA	P=0.0042*
Lateral articular cartilage injury	491 (40%)	156 (20%)	NA	64 (23%)	11 (12%)	P<0.0001*	P=0.0919	NA	P=0.0355*
Patellofemoral articular cartilage injury	506 (42%)	119 (15%)	NA	90 (32%)	2 (2%)	P<0.0001*	P=0.0012*	NA	P<0.0001*

*significant (p<0.05) value

the baseline clinical status evaluated with KOOS score was similar to the MARS registry, with non-clinically significant difference of 0 to 7 points for all the subscale *(25)*. This finding confirms the similarities between different revision populations as demonstrated by Magnussen et al. *(16)*, and also between different primary ACL reconstruction populations *(17)*. In the author's aim, the clinical score collected at pre-operative status, coupled with progressive completion of follow-up evaluations and continuous patients enrolment could be useful to understand the clinical course of the revision ACL reconstruction in the Italian population, with special regard to graft choice and cartilage or meniscal status.

Despite the multicentric and prospective nature, this study has several limitations. First of all, no systematic objective or radiologic evaluation was performed. However, this behaviour is partially shared with the other registries due to the difficulty in collect these data in systematic and homogeneous manner because of the large volume and the multicentric design. Despite this, the SIGASCOT members were invited to collect these data, and it not excluded that this could allow a specific evaluation in the future. Another limitation was that no information on previous graft or cause of primary ACL failure was collected. This was due to the lack of the possibility to compile such information within the outcomes collecting system (SOS). Due to the huge amount of the data that examiners were asked to collect, the implementation of a parallel form to collect also these missing variables was excluded to not overload the examiners.

Finally, the presence of missing data both from the examiner's and the patient's side could represent

a bias. However it is desirable that in the following years the data collection process could be improved after the initial learning curve.

CONCLUSIONS

During the first year of enrollment, the SIGASCOT Italian ACL revision registry was able to collect the data of more than 100 patients undergoing a revision procedure. The revision ACL reconstruction was usually performed with a single-bundle technique, using allograft and autograft almost in the same extent. Similarities in graft choice and basal status were present respect to the North American MARS registry. A high number of previous meniscetomies or new meniscal lesions was reported, frequently approached with conservative, reparative or substitutive procedures.

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