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GNRB (Medical Device) vs MRI on Anterior Cruciate Ligament (ACL) Tears with Arthroscopic Validation

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INTRODUCTION

Objective: comparison of GNRB® versus MRI in the diagnosis of different patterns of anterior cruciate ligament tears.

Requirements: patients operated for ACL tears or ACL tears + meniscus.

Exclusion Criteria: all patients without isolate ACL tears (without other ligament and bone injuries), patients were not get primary surgery.

Collection of Data: Database of Dr Henri ROBERT (surgeon, specialist on ACL surgery: operative report, MRI (1.5 T) report and GNRB database for all patients).

Group of patients

2 groups:

- Patients with complete ACL tears
- Patients with partial ACL tears

STATISTICAL TEST

We use sensibility like an indicator for average method.

Binary criteria: ACL tears (partial or complete)

Acceptability

For MRI report, if it required interpretation, it shall be null. It must be clearly mentioned complete or partial tears in the conclusion report.

For GNRB, if delta for both knees >3 mm = complete tears and if 1.5 mm ≤ delta <3 mm, partial tears.

Non Inferiority Test

Estimate value: P_r (MRI's sensibility [1]) by $\Pi_r = 0.57$

Estimate value: P_e (GNRB's sensibility [2,3]) by $\Pi_e = 0.84$

It set $\alpha = 5$ % unilateral, $\beta = 10$ % and $\delta = 10\%$.

Number Needed to Treat (NNT): $\frac{2(u\alpha+u\beta)^2\times[\Pi r(1-\Pi r)+\Pi r(1-\Pi e)]}{[(\Pi e-\Pi r)-\delta)]^2}$

$\frac{2(u\alpha+u\beta)^2\times[\Pi r(1-\Pi r)+\Pi r(1-\Pi e)]}{[(\Pi e-\Pi r)-\delta)]^2}$ = 34 subjects by group at the minimum ($n_t = 68$ subjects)

For estimation by confidence interval (CI) of difference of proportions:

With Pe = GNRB's sensibility and Pr = MRI's sensibility

And Ne = Nr

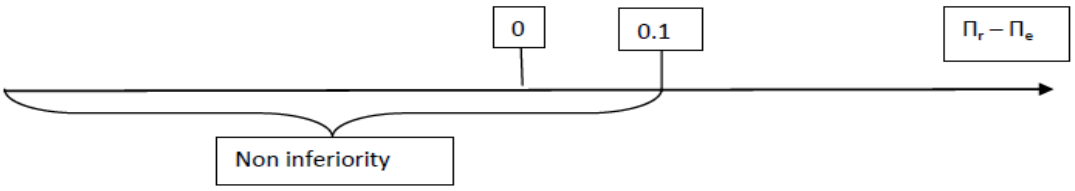
Condition for application

- $n_r, n_e \geq 30$
- $n_r p_r, n_r(1-p_r), n_e p_e, n_e(1-p_e) \geq 5$

Formula

$$(p_e - p_r) \pm u_\alpha \cdot \sqrt{\frac{p_e(1-p_e)}{n_e} + \frac{p_r(1-p_r)}{n_r}}$$

Pattern:



Difference of proportions test:

- Difference test at $\delta \neq 0$

$$z = \frac{(pe - pr) - \delta}{\sqrt{\frac{pe(1-pe)}{ne} + \frac{pr(1-pr)}{nr}}}$$

RESULTS

This study was performed on data from previous years and two years before for 200 operated patients in total. After exclusion of 64 medical files (one of the 3 data is missing : GNRB, MRI or arthroscopic report), 62 tears were partial and 74 complete with arthroscopy report.

Table1. *Table of IRM's and GNRB's sensibility with arthroscopy for reference*

	MRI vs arthroscopy for complete ACL	MRI vs arthroscopy for partial ACL	GNRB vs arthroscopy for complete ACL	GNRB vs arthroscopy for partial ACL
Number	**47**	**22**	**45**	**46**
Number of subject	**62**	**74**	**62**	**74**
Sensibility	**0,76**	**0,30**	**0,73**	**0,62**

For complete tears, MRI's sensibility was 0.76 and GNRB's sensibility 0.73.

For partial tears, MRI's sensibility was 0.30 and GNRB's sensibility 0.62.

For complete tears

For estimation by confidence interval (CI) of difference of proportions

Conditions for application are verified.

$$(pe - pr) + U\alpha \times \sqrt{\frac{pe(1-pe)}{ne} + \frac{pr(1-pr)}{nr}} = 0.0983$$

Difference test at $\delta \neq 0$

$$z = \frac{(pe-pr)-\delta}{\sqrt{\frac{pe\,(1-pe)}{ne} + \frac{pr\,(1-pr)}{nr}}} = -1.52$$

For partial tears [4]

For estimation by confidence interval (CI) of difference of proportions

Conditions for application are verified.

$$(pe - pr) + U\alpha \times \sqrt{\frac{pe(1-pe)}{ne} + \frac{pr(1-pr)}{nr}} = 0.4476$$

Difference test at $\delta \neq 0$

$$z = \frac{(pe-pr)-\delta}{\sqrt{\frac{pe\,(1-pe)}{ne} + \frac{pr\,(1-pr)}{nr}}} = 2.835$$

DISCUSSION

Table2. *Sensibility and specificity of GNRB in the litterature*

	Complete ACL		Partial ACL	
	Sensibility	**Specificity**	**Sensibility**	**Specificity**
Robert H [5]	**70%**	**99 %**	**80%**	**87%**
Klouche S [3]	**92%**	**96**	**92%**	**98%**
Di Ioro A			**72%**	**85%**
Lefevre N	**84%**	**81%**	**87%**	**87%**
Beldame J	**62%**	**75%**		
Beaurain F	**73%**		**62%**	

This results shows equivalence for ACL's complete diagnostics (for MRI and GNRB reports) with the literature and for incomplete ACL tears, it's slightly lower than literature.

Table3. *Sensibility of MRI in the literature*

	Complete ACL	Partial ACL
Beldame J [1]	**57%**	
Steltzlen C [4]		**32%**

Sensibility's results (for MRI and GNRB reports) for this study are equivalent for complete and partial tears diagnostic in the literature.

CONCLUSION

Sensibility of GNRB laximetry is quite the same than MRI for complete tears but superior for partial tears.

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