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TITLE PAGE

A prospective observational study on the variables affecting the risk of inferior alveolar nerve damage during lower third molar surgery with nerve/root proximity.

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Abstract

Purpose. The present study aimed to evaluate which factors were statistically associated with a greater probability of inferior alveolar nerve (IAN) damage during lower third molar surgery.

Methods. A prospective observational study was performed at the Oral Surgery Unit of the Umberto I Hospital on 92 patients which underwent surgical extraction of a lower third molar, that was radiographically overlapped with the mandibular canal. All surgeries were performed by the same expert surgeon. A principal component analysis and the exact 2-tailed Fisher test were used.

Results. Temporary IAN damage occurred in 10 cases (10.9%). Symptoms lasted from 18 to 180 days (73±49.15). IAN damage was more frequent in difficult and long-lasting surgeries, in the presence of many risk factors and in patients with a reduced maximum mouth opening.

Conclusion. Such factors should be accurately evaluated before surgery to assess and discuss the overall surgical risk of IAN damage with the patient especially when they are over the maximum limit of their significant variability range found in the present study, that is, >12 for difficulty index, >2 for number of OPG risk markers and <3.7 cm for maximum mouth opening.

Introduction

Lower third molar surgery is 1 of the most common oral and maxillofacial surgical procedures and is burdened by a risk of inferior alveolar nerve (IAN) damage in up to 13.2% of cases[1], although damage is rarely permanent (0.12%)[2].

IAN proximity to third molar roots is certainly the most important predisposing factor for nerve damage and an unusual relationship is also possible regardless of type and depth of third molar impaction[3].

Many authors found a positive correlation between specific radiographic signs and IAN damage, such as mandibular canal deviation, root darkening and interruption of the upper cortical line[1,4-8].

Coronectomy has been widely proposed to eliminate the risk of nerve damage by leaving the tooth root near the IAN in situ[9], but this technique is burdened by the prognostic uncertainty related to the residual tooth portion[10].

Awareness of which factors are most capable of exposing the patient to risk of nerve damage is therefore of paramount importance to correctly plan surgical procedures which avoid or minimize IAN injury, and to provide the patient with clear and comprehensible information regarding the risks of the procedure.

The present study aimed to evaluate which factors were statistically associated with a greater probability of IAN damage during lower third molar surgery in cases with IAN-third molar root proximity.

Methods

A prospective observational study was performed at the Oral Surgery Unit of the Umberto I Hospital, Department of Odontostomatological and Maxillofacial Sciences, Sapienza University of Rome.

The study was approved by the local Ethical Committee with protocol number 4111 and followed the principles of the Declaration of Helsinki, October 2013 and was registered on ClinicalTrials.gov (Identifier: NCT4314726).

Inclusion criteria were the following:

- orthopantomographic superimposition between the lower third molar and at least the upper half of the mandibular canal, associated or not with the presence of 1 or more radiographic signs of proximity among those proposed by Rood and Shehab (1990)[4]:
- 3-dimensional radiographic examination with a CT software;
- any type of lower third molar impaction (bone/osteomucosal/partial).

Exclusion criteria were the following:

- lower third molar buds;
- lack of contiguous second molar;
- wide cyst-like areas or severe osteo-metabolic/tumor pathologies associated with the lower third molar;
- pre-operative neurosensory deficit related to IAN on the side where surgery was to be performed.

Patients were enrolled only after giving consent to participate in the study. Consent to statistical treatment of clinical and radiographic data was also obtained from all patients.

The following groups of factors were taken into consideration:

- factors related to the patient: gender, age, body mass index (BMI);
- radiographic factors: risk markers, position and changes in IAN position compared to the third molar, presence/absence of a cortex between IAN and third molar, third molar position and root morphology, Pell & Gregory class, impaction depth;
- clinical factors: intra-operative IAN exposure (yes/no), intra-operative complications, such as root and bone fracture/hemorrhage (yes/no), nerve impression on the tooth root (yes/no), type of impaction, maximum mouth opening;
- factors related to surgery: duration, difficulty index.

Clinical and radiographic data were noted on a special chart, developed in 4 areas concerning the patient's personal data, pre-operative case evaluation, surgical technique, and post-operative course.

Radiographic evaluations were independently performed by 2 different surgeons (RP, AP). In cases of different interpretation, the evaluation of a third investigator was scheduled.

Surgery duration was timed by an external assistant, from the soft tissue incision to the end of suturing.

Assessment of surgical difficulty was reached using a modified Pederson's scale by assigning a 1 to 3 score to each of the following variables: tooth inclination (mesioangular/vertical=1; horizontal=2; distoangular=3), depth of impaction (modified Winter classification: A/B=1; C1=2; C2=3), Pell & Gregory class (I=1; II=2; III=3), root morphology (fused or slightly divergent=1; strongly divergent=2; presence of apical anomalies=3), proximity to the IAN (none=1; contiguity=2; embrication=3) and maximum mouth opening (>4 cm=1; 3-4 cm=2; <3 cm=3). For each extracted third molar, a total score between 6 and 18 was therefore obtained.

All surgeries were performed by the same expert surgeon (RP), with the buccal approach using local anesthesia, and included the following maneuvers:

- Tooth section, when deemed necessary, with 1 or more section lines, using a 18/21 round bur, with a turbine;
- luxation of the coronal portion of the tooth/root in an ipsilateral or parallel direction with respect to the IAN position and running, in order to minimize nerve compression;
- post-extraction residual bone cavity inspection using a Zeiss 4x300 magnification optical system to better identify intra-operative nerve exposure.

No material was inserted into the residual cavity, neither by regeneration nor by hemostasis.

After 1 week, sensitivity was tested on both sides with the tactile test using a 27-gauge needle tip and, if a difference was found, the patient was followed once a week for the first month and every 2 weeks thereafter until he/she reported to perceive the pin-prick test in the affected side the same way as the healthy side.

Sample size was previously calculated using data on surgery duration obtained from the study by Pippi and Santoro[10], in which this variable was found to be positively and significantly correlated to the risk of nerve damage. It was thus calculated that a sample of 92 patients would have reached a 99% power (alpha=0.01) in identifying an odds ratio of 5.5 and in rejecting the null hypothesis (P1=2/52=0.038) that surgeries lasting more than 20 minutes had the same probability of determining nerve injury than those lasting less than or equal to 20 minutes, using a 1-tailed binomial test.

Statistical methods

A principal component analysis (PCA) was initially performed on the 7 quantitative explanatory variables: patient age, BMI, maximum mouth opening, number of roots, number of radiographic risk signs, duration of surgery, and difficulty of surgery. The exact 2-tailed Fisher test was used to evaluate the effect of the 15 qualitative explanatory variables on the probability/risk of injury to the IAN: patient gender, tooth number, Pell & Gregory class, type of impaction, depth of impaction, tooth position, root morphology, mandibular canal cortex integrity, IAN/tooth proximity, presence of apical root anomalies, intra-operatively detected anomalies, intra-operative exposure of IAN, tooth sectioning, and occurrence of intra-operative accidents. The significance level for these analyses was set α=0.05. The Holm-Bonferroni sequential correction method was finally applied to compensate for the increased probability of finding false positives, which is typical when a series of multiple comparisons on the same dependent variable is performed. In this method, each individual hypothesis is re-tested at a significance level of α/k_i, in which α is the level of statistical significance and ki is the number of remaining hypotheses to be tested (α=0.05 and ki=19… 1). Statistical analyses were performed using R v3.6.2 software (R core team 2019).

Results

Descriptive analysis

All data of the study sample are reported in Table 1. Ninety-two lower third molars were completely extracted from 80 patients since 12 patients underwent 2 different procedures at different times, each 1 for the removal of 1 lower third molar. Surgeries were performed from April 1, 2016 to January 29, 2019. Temporary IAN damage occurred in 10 cases (10.9%). Symptoms lasted from 18 to 180 days (73±49.15; Table 2). Sixty-eight third molars (73.9%) were in Pell and Gregory III class, 50 (54.3%) were mesially inclined and in 51 cases (55.4%) the IAN was lingual to the root.

Inferential analysis

The first 4 components of the PCA (Table 3) account for the 73.95% of the total data variability and therefore can be used as summary indices of the following 7 original variables: patient age, BMI, maximum mouth opening, root number, number of OPG risk signs, surgery duration, and difficulty index.

The first principal component (PC1) is positively correlated to the difficulty score and, to a lesser extent, to both the duration of surgery and the number of radiographic risk signs. Furthermore, PC1 is negatively correlated to the patient's maximum mouth opening (Table 4). In other words, the PC1 index has high values in difficult and long-lasting surgeries, in the presence of many risk factors and in patients with a reduced maximum mouth opening. Since all these factors are collectively associated with procedures of a greater difficulty, the PC1 index can be considered an index of surgical difficulty.

The second principal component (PC2) is positively correlated to BMI and the age of patients (Table 4). In other words, PC2 (age-BMI index) has high values for older patients with a high BMI.

The third principal component (PC3) shows a strong positive correlation with the number of roots (Table 4). This means that teeth with high PC3 (root number index) scores have more than 1 root.

The fourth principal component (PC4) shows a strong positive correlation with the number of radiographic risk signs (Table 4). This means that teeth with high PC4 (risk factor number) scores are associated with a great number of risk factors.

Out of all 19 variables considered in the inferential analyses, only the PC1 and PC2 appear to have a significant effect on the incidence of IAN damage during lower third molar surgery (Table 5).

The difficulty index values of surgeries in which IAN damage occurred (1.23±1.79, μ±sd) are significantly higher than surgeries in which no IAN damage occurred (-0.15±1.18, μ±sd; $t_{(90)}$=3.27, p=0.0015; Figure 1). In other words, IAN damage was more frequent in difficult and long-lasting surgeries, in the presence of many risk factors and in patients with a reduced maximum mouth opening (Table 2).

The age-BMI values in surgeries in which IAN damage occurred (0.64±1.13, μ±sd) are significantly higher than the procedures in which there was no IAN damage (-0.08±1.19, μ±sd; U=246, p= 0.04; Figure 2). In other words, IAN damage was more frequent in older patients and in patients with a high BMI.

Sequential Holm-Bonferroni correction on 19 multiple comparisons confirms the statistical significance on the incidence of IAN damage for the difficulty index (0.0015<0.0026) but not for the age-BMI index (0.04>0.0028).

Discussion

IAN damage in the present study was always temporary and showed an incidence (10.9%) which was within the literature-reported range (0.35%[2]-13.4%[1]), but towards its upper limit, possibly because all involved lower third molars had a relatively high risk of nerve injury due to the closeness between their roots and IAN, considering that lower third molars required an OPG overlap with at least 50% of the mandibular canal width in order to be included in the study sample[10].

Variables related to PC1, that is, difficulty degree score, duration of surgery, number of radiographic risk signs, and maximum mouth opening, showed a significant effect on IAN damage incidence during lower third molar surgery with an OPG root/IAN superimposition.

Few studies analyzed the correlation between Pederson's index of surgical difficulty and IAN damage. The present results support those of Pippi and Santoro[10] and Jerjes et al [5] since IAN damage was found to be positively correlated to the objective evaluation of surgical difficulty degree with an overall score of 9.7±1.77 (Table 2), although, contrary to the study of Jeries et al [5], the total score included the mouth opening score in addition to tooth anatomical and morphological variables.

Results of the present study concerning the duration of surgery support those of Pippi and Santoro[10], Valmaseda-Castellón et al [11] and Jain et al [12], whereas they do not support those of Qi et al[13]. Actually, surgeries with nerve damage had an average duration of 1461±859 sec., which was longer than that of the entire sample (782±511), although in the study of Jain et al [12] the duration times of surgeries were lower (range: 600-2,520 sec.) than those of the present study. This difference can be explained by considering that the study sample of Jain et al [12] was randomized into 2 groups, in one of which tooth sectioning, which usually takes longer, was not performed, although the duration of each group of surgeries was not indicated, whereas, in the present study, tooth sectioning was more often performed (89.1%) with a much longer mean surgery duration of cases (828±520 sec.) compared to the duration of cases in which tooth sectioning was not performed (407±162 sec.).

Although PCA factors are uncorrelated to each other, it is not strange to have found that both surgery duration and difficulty were correlated to the risk of nerve injuries since the duration of surgery has been commonly used as a parameter of surgical difficulty.

As for the radiographic markers, the present study did not aim to verify the significance of each of them but aimed to assess the influence that the number of markers, simultaneously present in the same case, had on the incidence of IAN injury. The number of radiographic risk markers was significantly correlated to IAN damage in the present study as well as in a previous one by Leung and Cheung[7], with 2 or more radiographic signs significantly associated with IAN damage.

Maximum mouth opening has not been commonly investigated in the literature as a risk factor for nerve damage whereas it has been investigated as a risk factor for the difficulty of lower third molar surgery by several authors[14,15]. Pippi and Santoro already found mouth opening to be negatively related to IAN damage in a According to a multivariate retrospective study[10], mouth opening was presently In the present study, mouth opening was found inversely and significantly correlated to IAN damage, although the sample had a mean value for this_variable (4.48±0.73) with very little difference from that of cases with IAN damage (4.12±0.32). Actually, as the inter-incisor distance decreases, the surgeon's ability to perform pre-established surgical maneuvers, such as correctly directing the luxation action and controlling its intensity, also decreases, thus further exposing the patient to nerve damage.

All other variables considered in the present study were not significantly related to the risk of nerve damage, although, in previous studies some of them were.

To the best of the authors' knowledge, no studies have yet evaluated the correlation between BMI and the risk of IAN damage. In the present study, maximum mouth opening, and duration of surgery were significantly correlated to IAN damage. BMI was related as well, although the correlation was not statistically significant. Although PCA factors are directly uncorrelated to each other, these 3 factors may be indirectly related to each other since BMI is possibly related to both mouth opening and surgical difficulty, in relation to cheek distensibility, which is correlated to a more difficult or easier access to the surgical site and, consequently, to the length of surgery[15-17].

The present study also found a positive, but not significant, correlation between age and the risk of IAN injury, in line with other studies[2], contrarily to many previous ones[11,18,19].

The correlation between patient age and IAN damage is likely to be related to some characteristics that progressively appear with age, including completion of apical morphology, a greater bone density and a reduced bone elasticity, which all make a more complex and longer procedure necessary[18].

The number of roots also showed a positive, but not significant, correlation to IAN damage in the present study. This variable has not been frequently investigated in previous studies; however, it was found to be significantly related to IAN damage in both the retrospective studies of Jeries et al [5] and Pippi and Santoro.[10] On the contrary, Selvi et al [20] considered the number of roots which determined a cortical canal perforation, but this variable was uncorrelated with IAN damage anyway.

According to Pippi and Santoro[10] and Valmaseda-Castellón et al [11], and differently from many other authors[1,4,6], the radiographic discontinuity of the mandibular canal cortex was found not to be associated with an increased risk of nerve damage. Moreover, and contrary to other studies[1,21,22], not even an intra-operative IAN exposure was significantly related to nerve injury and cannot therefore be considered a "warning signal" for nerve injury but only a clinical confirmation of tooth/nerve proximity which can be concealed by several conditions such as inclination of the alveolar walls or blood clotting above the nerve[10]. The use of an optical magnification system which may improve visibility of small and deep areas of nerve exposure, is not mentioned in most studies. Although the lack of bone interposition may expose the nerve to a greater risk of damage, the surgical technique used in the present study, as well as in that of Pippi and Santoro[10], involved ipsilateral and/or parallel coronal dislocation in relation to the nerve position in order to limit nerve compression as much as possible[10], whereas the direction of luxation was described only by Qi et al [13] as opposed to other studies in which a positive statistical association with the cortex discontinuity[20,21] or IAN exposure[7] was reported.

Some authors also studied the role of the size of the IAN cortical-free area[7,13,19,20] and its position in relation to the third molar root length and morphology[13] in determining IAN damage, and found that the risk of nerve damage was significantly related to the size of the decorticated area[7,13,19,20] and to the lateral position of IAN at the level of an enlarged portion of the root[13].

Although all this information can only be obtained by CT images, they have been recently found to be unable to reduce IAN damage incidence compared to OPG[23] and no CT signs, such as IAN/tooth relationship and cortical interruptions, were found to be related to IAN damage in the present study. However, since in medico-legal litigations the court judge usually asks whether all pre-operative auxiliary examinations, which contribute to better clarify the clinical picture, thus helping to avoid damage, were performed, a more comprehensive pre-operative assessment should be performed in case a preliminary OPG is unable to clarify such signs, in order to improve medical behavior based on diligence[10].

Finally, although Jain et al [12] found that tooth sectioning was useful in significantly reducing IAN damage incidence in lower third molar surgery, the present study supports the study of Cheung et al

[2] in that it does not confirm this finding, possibly because the Jain et al study[12] was randomized for tooth sectioning, whereas in the present study, and in that of Cheung et al [2], surgeon chose to carry out tooth sectioning only when strictly necessary.

In conclusion, some patient and tooth pre-operative variables, including maximum mouth opening, difficulty index, and number of risk radiographic signs, were significantly correlated to IAN damage during lower third molar surgery when a superimposition of root and IAN was recognizable on the OPG. Since the significance of correlation is within a very limited range of the present sample variability, these factors should be accurately evaluated before surgery to assess and discuss the overall surgical risk of IAN damage with the patient, especially when they are over the maximum limit of their significant variability range found in the present study, that is, > 12 for difficulty index, > 2 for number of OPG risk markers and < 3.7 cm for maximum mouth opening. Tooth sectioning, intra-operative IAN exposure, and radiographic discontinuity of the mandibular canal cortex were not related to IAN damage.

Study limitations

Some results in this study, including mouth opening, BMI, difficulty index, and length of surgery, cannot be generalizable for surgeons with different degrees of experience since all the procedures were performed by a single expert surgeon.

In the present study CT imaging was performed in various facilities, thus with different equipment and software since patients with difficult cases were often referred to the Oral Surgery Unit by general dentists, therefore a complete preliminary evaluation had usually already been carried out. Although a perfect detection of the mandibular canal is essential in order for an exam to be considered adequate enough to be used in planning third molar surgery, differences can exist between 1 exam and another in detail definition of both root morphology and mandibular canal cortical cortex, so a study in which the same equipment and software are used, with the same execution parameters, may be useful in making radiographic data of the exams efficiently comparable to one another.

The tactile test used in the present study for sensitivity impairment assessment allowed only to assess the time for sensitivity recovery, but further tests should be used for quantitative evaluation of residual IAN function, especially in more severe cases.

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Table 1. Study sample variables

VARIABLES		THIRD MOLARS N (%)
Patient: gender	M	44 (47.8)
	F	48 (52.2)
mean age ± sd (range)	26.38 ± 8.76 (16-54)	
mean BMI ± sd (range)	22.92 ± 3.42 (17-40)	
mouth opening ± sd (range)	4.48 ± 0.73 (2-6)	
Third molar: inclination	Mesial	50 (54.3)
	Vertical	19 (20.7)
	Horizontal	19 (20.7)
	Distal	4 (4.3)
Pell & Gregory's class	I	19 (20.7)
	II	5 (5.4)
	III	68 (73.9)
impaction depth	a/b	79 (85.9)
	C	13 (14.1)
impaction type	Bone	6 (6.5)
	Osteo-mucosal	52 (56.5)
	Partial	34 (37.0)
root morphology	A	18 (19.6)
	B	59 (64.1)
	C	15 (16.3)
root number	1	4 (4.3)
	2	79 (85.9)
	>2	9 (9.8)
relationship with the IAN	1	89 (96.7)
	2	3 (3.3)
IAN/3M position	Lingual	51 (55.4)
	Buccal	33 (35.9)
	Changing	8 (8.7)
Number of OPG risk signs	0	9 (9.8)
	1	50 (54.3)
	2	24 (26.1)
	3	8 (8.7)
	4	1 (1.1)
IAN canal wall	Continuous	58 (63.0)
	Interrupted	34 (37.0)
Apical anomalies	Yes	33 (35.9)
	No	59 (64.1)
Intra-operative root anomalies	Discrepancy	10 (10.9)
	No	61 (66.3)
	IAN impression on the root	21 (22.8)
Mean difficulty index ± sd (range) (6-18 scale)	9.4 ± 1.3 (7-12)	
Mean surgical time (sec.) ± sd (range)	782 ± 511 (146-3300)	
IAN surgical exposure	Yes	36 (39.1)
	No	56 (60.9)
Tooth section	Yes	82 (89.1)
	No	10 (10.9)
Intra-operative complications	Yes	15 (16.3)
	No	77 (83.7)
Nerve impairments	Yes	10 (10.9)
	No	82 (89.1)

BMI: body mass index; IAN: inferior alveolar nerve

Table 2. Principal variables of cases with inferior alveolar nerve damage

VARIABLES	MEAN ± SD	RANGE
N = 10 (F:6; M:4)		
Time to sensitivity recovery (days)	73 ± 49.15	18 - 180
Patient age	30 ± 7.85	20 - 49
Patient BMI	23.75 ± 3.52	19.07 - 29.76
Mouth opening (cm)*	4.12 ± 0.32	3.7 - 4.5
Number of OPG risk signs*	1.8 ± 0.84	
Root number	2.2 ± 0.63	
Surgical time (sec.)*	1,461 ± 859	564 - 3,300
Difficulty index (6-18 scale)*	**9.4 ± 1.4**	7 - 12

BMI: body mass index; OPG: ortopantomography
***Variables with significant correlation**

Table 3. Principal component analysis eigenvalues

PCA				
	PC1	PC2	PC3	PC4
Eigenvalues	1.72	1.42	1.12	0.91
Variance (%)	24.62	20.31	16.06	12.97
Cumulative variance (%)	24.62	44.92	60.98	73.95

PCA: Principal Component Analysis

Table 4. Quantitative variable correlation with the first 4 principal components (PC). Significant values are highlighted in bold

Variables	PC1	PC2	PC3	PC4
Age	0.5	**0.63**	-0.31	-0.15
BMI	-0.11	**0.84**	-0.21	0.09
Maximum mouth opening	**-0.61**	0.3	0.37	0.43
N. of roots	-0.04	0.27	**0.83**	-0.32
N. of radiographic markers	**0.54**	-0.13	0.11	**0.74**
Surgery duration	**0.52**	0.34	0.3	0.12
Surgical difficulty	**0.72**	-0.19	0.25	-0.17

BMI: body mass index

Table 5. Effect of variables on IAN damage ccurrence. Significant values are highlighted in bold

Variables	Test	Statistics	p-value	$p < 0.05$
PC1	**t-test**	**$t_{(90)} = 3.274$**	**0.0015**	*
PC2	**Mann-Whitney U-test**	**U = 246**	**0.0403**	*
PC3	t-test	$t_{(90)} = 1.405$	0.1636	
PC4	t-test	$t_{(90)} = 0.457$	0.6486	
Impaction type	Fisher's exact test	-	0.0598	
Third molar code	Fisher's exact test	-	0.096	
IAN intra-operative exposure	Fisher's exact test	-	0.1813	
IAN/tooth relationship	Fisher's exact test	-	0.2948	
Intra-operatively found anomalies	Fisher's exact test	-	0.4458	
IAN position	Fisher's exact test	-	0.5172	
Third molar position	Fisher's exact test	-	0.5185	
Impaction depth	Fisher's exact test	-	0.6289	
Intra-operative accident occurrence	Fisher's exact test	-	0.6644	
Pell & Gregory class	Fisher's exact test	-	0.6944	
Apical root anomalies	Fisher's exact test	-	0.7419	
Patient gender	Fisher's exact test	-	0.7421	
Root morphology	Fisher's exact test	-	0.8914	
Mandibular canal cortex integrity	Fisher's exact test	-	1	
Tooth section	Fisher's exact test	-	1	

Figure legends

Figure 1. Surgical difficulty index boxplot (*Mdn*, IQR, ±1.5*IQR) in the absence and in the presence of IAN damage (n_1=82, n_2=10, N=92).

Figure 2. Age-BMI index boxplot (*Mdn*, IQR, ±1.5*IQR) in the absence and in the presence of IAN damage (n_1=82, n_2=10, N=92).

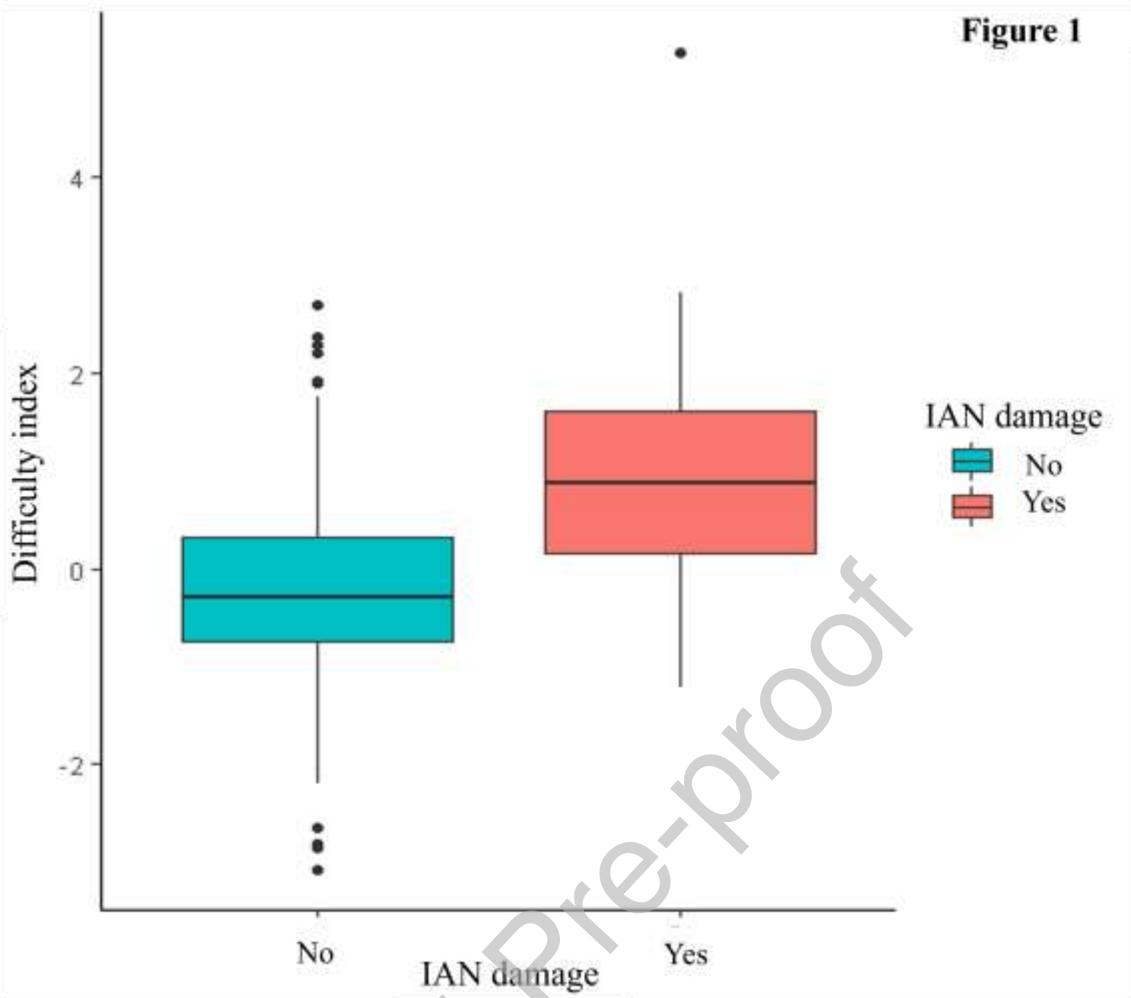
Figure 1
Difficulty index
4
2
0
-2
No
Yes
IAN damage
IAN damage
No
Yes

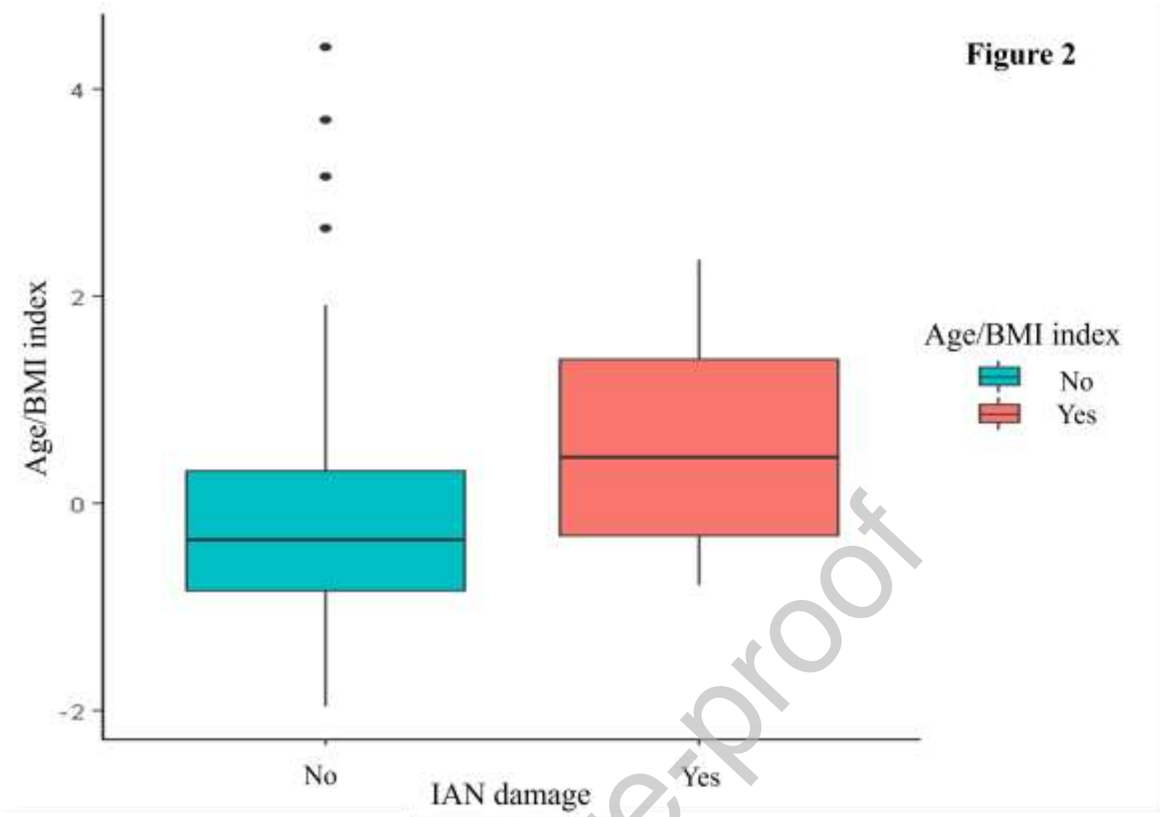
Figure 2
Age/BMI index
4
2
0
-2
No
Yes
IAN damage
Age/BMI index
No
Yes