JOINTS 2023; 1: e726

Category: Original Article

CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE ITALIAN VERSION OF HIP OUTCOME SCORE (HOS) IN PATIENTS WITH FEMOROACETABULAR IMPINGEMENT

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ABSTRACT – *Objective:* Femoroacetabular Impingement (FAI) is a common condition in the European population, leading to discomfort in daily and sports activities. To date, no outcome measure is validated in the Italian language for the assessment of this condition. The purpose of this study was to translate the Hip Outcome Score (HOS) into Italian language and to evaluate the psychometric properties by testing the construct validity, internal consistency, and reproducibility, in patients undergoing hip arthroscopy for FAI.

Materials and Methods: The English version of HOS was translated in Italian and evaluated for psychometric properties in Italian-speaking patients undergoing hip arthroscopy for FAI. Construct validity was investigated by means of regression analysis with the modified Harris Hip Score (MMHS), Oxford Hip Score (OHS), and visual analogue scale (VAS) for pain. Test-retest reliability was evaluated through the intraclass correlation coefficient (ICC). Floor and ceiling effect and Cronbach's Alpha were calculated to assess internal consistency.

Results: A total of 45 patients were recruited with a mean age of 33.3 (95% CI: 30.8, 35.7) years. Correlation analysis showed statistically significant positive concordance with MMHS (p=0.001), OHS (p=0.002), and significant negative concordance with VAS for pain (p<0.001). Intraclass correlation coefficients were excellent for the ADL subscale (ICC average 0.99, 95% CI: 0.99, 0.99) and for the sport subscale (ICC average 0.99, 95% CI: 0.99, 0.99). Cronbach's alpha was over 0.9 for both subscales, and no floor or ceiling effect was found.

Conclusions: The Italian HOS questionnaire is valid, reliable, and responsive for use in Italian patients undergoing hip arthroscopy for FAI. This tool represents a valuable patient-reported outcome for international clinical investigations involving patients with FAI.

KEYWORDS: Hip, Hip arthroscopy, Femoacetabular impingement, Hip outcome score.

INTRODUCTION

Femoroacetabular impingement (FAI) has been widely documented[1-3] as a cause of groin pain and as a precursor of irreversible degenerative joint disease of the hip. For this condition, hip arthroscopy is generally advocated, to surgically address bony impingement and possible soft tissue repair[2]. This kind of surgery is commonly aimed at preventing long-term degenerative hip conditions in young, active subjects[3]. As this population has a younger age and more active lifestyle than the population undergoing hip arthroplasty, patient-reported outcome measures (PROMs) for this procedure consider some specific activity domains, that are not accounted for in other measures used for assessing outcomes of arthroplasty. Some attempts of modification of arthroplasty-focused outcome measures (modified Harris Hip Score, MMHS) have been made, to use the same measures for hip arthroscopy outcomes[4]. However, HHS is only partially patient-reported, and thus it cannot be considered a PROM[5]. The Hip Outcome Score (HOS) is a PROM developed for the specific purpose of assessing arthroscopy outcomes, and its validity was demonstrated in 2007 by Martin et al[6] and Martin and Philippon[7], and trans-cultural adaptation and translation have already been provided in several languages[8-12]. It has been recently reported[5] that HOS, and not modified HHS, is a reliable assessment tool for patients affected by FAI and clinically meaningful thresholds have been proposed[13]. Furthermore, a systematic review[14] reported that the HOS represents, among others, the most reliable tool for assessing hip and groin disability. FAI is a high-prevalence condition in Europe, requiring clinical research in the field, to improve clinical management and develop therapeutic strategies in the active population; thus, there is a need for an internationally validated tool to assess patient outcomes. In order to investigate clinical outcomes for this surgery in the Italian population, to internationally compare research results, and to perform global trials, a valid and internationally available PROM is required. The main hypothesis of the present study was that an Italian translation of HOS represented a consistent, valid and reliable tool for the assessment of outcomes of Italian patients undergoing hip arthroscopy for FAI. The main endpoint of the present investigation was to provide a translation of HOS in the Italian language and to investigate the external consistency of the construct through correlation with other known outcome measures for hip disease. Secondary endpoints were the investigation of test-retest reliability and internal consistency of the Italian version of HOS.

MATERIALS AND METHODS

Cross-Cultural Adaptation

The translation followed the recommendations for the cross-cultural adaptation of self-reported measures[15]. Forward translation of the HOS was independently carried out by two informed translators, orthopedic surgeons, a native Italian speaker with fluent English, and one professional bilingual translator, a native Italian speaker, with full proficiency in English, naïve to the PROM. The first version was obtained after a consensus meeting of the three translators. Two native English speakers fluent in Italian and with medical background were blinded to the original English version and translated this provisional Italian version back into English. This back translation was reviewed against the source by a second consensus meeting of all persons involved in the translation process in order to check for discrepancies or any problems. The final Italian version was obtained after testing it on 20 patients with FAI to ascertain that there were no issues with comprehension of the questionnaire content.

Population

A total of 45 patients were enrolled in the study. The sample was recruited in an orthopaedics outpatients clinic when they were diagnosed with FAI by an orthopaedic surgeon, based on radiologic (X-rays and high field MRI) and clinical evidence and referred for hip arthroscopy. Each patient gave written informed consent to participate in this study and for the use of clinical data for research purposes. Subjects were excluded if they were unable to understand the Italian written language, if they had inflammatory arthritis, hip osteoarthritis (OA) or symptomatic OA in other lower limb joints. Medical and surgical records were reviewed to collect information on the surgical procedures performed, age, and gender.

Outcomes Assessment Procedures

Patients were asked to fill out the Italian version of the HOS, the Modified Harris Hip Score (MMHS), the Oxford Hip Score (OHS), and a visual analogue scale (VAS) for pain after clinical evaluation. The validated Italian-language versions of these measures were used[16,17]. An electronic version of the HOS score was sent to the patients by email, two weeks after the first assessment, and answers were collected through a phone interview. Two weeks were considered an acceptable time to ensure that the clinical situation would not have changed during this period. In addition, the interviewer asked for any changes in clinical conditions. Furthermore, the patients were asked not to undergo any treatment in the two-week period.

The HOS has two separately scored subscales: the activities of daily living (ADL) subscale with 19 items, 17 of which are scored, and the sport subscale with 9 items. ADL and sports subscales generate two individual subscores ranging between 0 and 100, where the higher the score, the better the outcome.

The MMHS is a 3-section score, each of which is composed of 1-4 questions investigating perceived hip pain, gait quality and support needed, and functional activities in daily life[16]. The score ranges between 0 and 100 (summed items), with a higher score corresponding to a higher perceived hip function.

The OHS comprises 12 items assessing pain and disability of the hip[16]. Each item is rated on a 0- to 4- Likert scale. The measure generates a single overall score ranging between 0 and 48 (summed items), with higher scores representing the best health state.

The VAS for pain is a simple way of assessing the intensity of pain. The 0-100 mm-VAS is widely used, and it is classically considered to be valid and reliable[18]. Higher pain corresponds to higher VAS values.

External Construct Validity

Evidence for cross-sectional construct validity must be accumulated by *a priori* hypothesized pattern of associations with other validated instruments, which purport to measure relatively similar constructs (for positive and negative correlations)[19,20]. Hamilton's robust regression model was used for calculating the correlation coefficient, to assess the association between HOS subscales with OHS, MMHS, and VAS for pain. It was hypothesized *a priori* that the total HOS, OHS, MMHS, and VAS for pain were strongly correlated, with a positive correlation of HOS with OHS and MMHS and a negative correlation with VAS for pain.

Test-Retest Reliability

The intraclass correlation coefficient (ICC) was calculated using a one-way random-effects model, according to Shrout and Fleiss[21], for repeated assessment of the same target. Average and individual coefficients were calculated, with a 95% confidence interval (95% CI). An ICC higher than 0.80 is commonly considered an indicator of good reproducibility[21,22].

Internal Consistency

Floor and ceiling effects were calculated by finding the clusters for "worst" and "best" outcomes. The clusters were obtained from minimum (end anchor) and maximum (best anchor) values, adding or subtracting the Minimal Detectable Change (MDC), respectively. The MDC correction was used to adjust the floor and ceiling values to account for measurement error and was calculated as Standard Error of Measurement (SEM) x 1.41 x 1.9, as reported in previous literature[10]. A floor or ceiling effect was considered if the anchor cluster contained more than 15% of the population.

Cronbach's Alpha[23] was used for internal variability assessment. Values equal to or above 0.7 indicated acceptable reliability for scales which are used as research tools to compare groups[24,25]. Both the floor and ceiling effects and Cronbach's Alpha were assessed for the ADL subscale and the sport subscale.

Statistical Analysis

Database completeness and consistency were checked before formal analysis. No missing data were found within the series. Data were summarized using raw frequency and percentage for binomial series and mean, standard error, and 95% Confidence Interval (95% CI) for continuous variables. Given the sample size and endpoints, a conventional threshold of significance was set with p=0.05. In accordance with previous literature, a minimum acceptable value for ICC was 0.75, and a sample size of 25 patients was considered sufficient to achieve an 80% power (beta=0.2, alpha=0.05)[10,26]. Data were analyzed using STATA vers. 17.0 (Stata Corp, College Station, Texas, USA).

RESULTS

A total of 45 subjects undergoing hip arthroscopy for FAI were included in the study. The diagnosis was CAM FAI in 33 patients (73.3%), of which 17 had associated labral tear (37.7%), mixed FAI in 5 patients (11.1%), a post-traumatic lesion of the femoral head in 2 patients (4.4%), a labral tear in 1 patient (2.2%), other diagnoses in the remaining 4 patients. All patients completed the questionnaire (both ADL and sports subscales) at each time points. No missing data were found in the questionnaire review and data entry. The mean age of the cohort was 33.3 (SE 1.2, 95% CI: 30.8, 35.7) years, 28 (62%) were males, and 17 (38%) were females. Average HOS scores at first and second measurements and average OHS, MMHS, and VAS scores are summarized in Table 1.

Table 1. Descriptive statistics.

Variable	Proportion			
Sex (M:F)	28:17			
Variable	**Mean**	**Std. Err.**	**95% CI**	
Age (years)	33.33333	1.214392	30.88589	35.78078
HOS ADL	70.684	2.3227	66.00291	75.36509
HOS Sport	46.25222	3.274536	39.65283	52.85161
HOS ADL 2nd assessment	70.68756	2.324938	66.00195	75.37316
HOS Sport 2nd assessment	46.034	3.249142	39.48578	52.58222
MMHS	68.48444	1.682245	65.0941	71.87479
OHS	34.33333	1.179796	31.95561	36.71106
VAS	4.733333	0.305505	4.117628	5.349038

Regression analysis showed a positive statistically significant correlation of the HOS ADL with MMHS (beta=0.81, p<0.001) and OHS (beta=1.27, p<0.001) and a negative statistically significant correlation with VAS for pain (beta=-3.09, p=0.006), using both series of measurements of total HOS. The sport subscale presented a correlation, though not significant, with OHS (beta=0.7, p=0.113). Details of correlation analysis, including correlation coefficients, are reported in Table 2 and Figure 1.

Table 2. Correlation analysis for external validity.

	Coefficient	SEM	95% CI		*p*-value
HOS ADL					
MMHS	.8100627	.1705102	.466196	1.153929	0.000**
OHS	1.266295	.2298834	.8026913	1.729899	0.000**
VAS	-3.091732	1.059224	-5.227861	-.9556029	0.006*
HOS Sport					
MMHS	.6608138	.2792137	.0977257	1.223902	0.023*
OHS	.6656664	.4109077	-.163008	1.494341	0.113
VAS	-5.797962	1.37476	-8.570429	-3.025494	0.000**

HOS: Hip Outcome Score, ADL: Activity of Daily Living, SEM: Standard Error of the Mean (of Measurement), 95% CI: 95% Confidence Interval, MMHS: Modified Harris Hip Score, OHS: Oxford Hip Score, VAS: Visual Analog Scale. *Statistically significant, **Highly statistically significant.

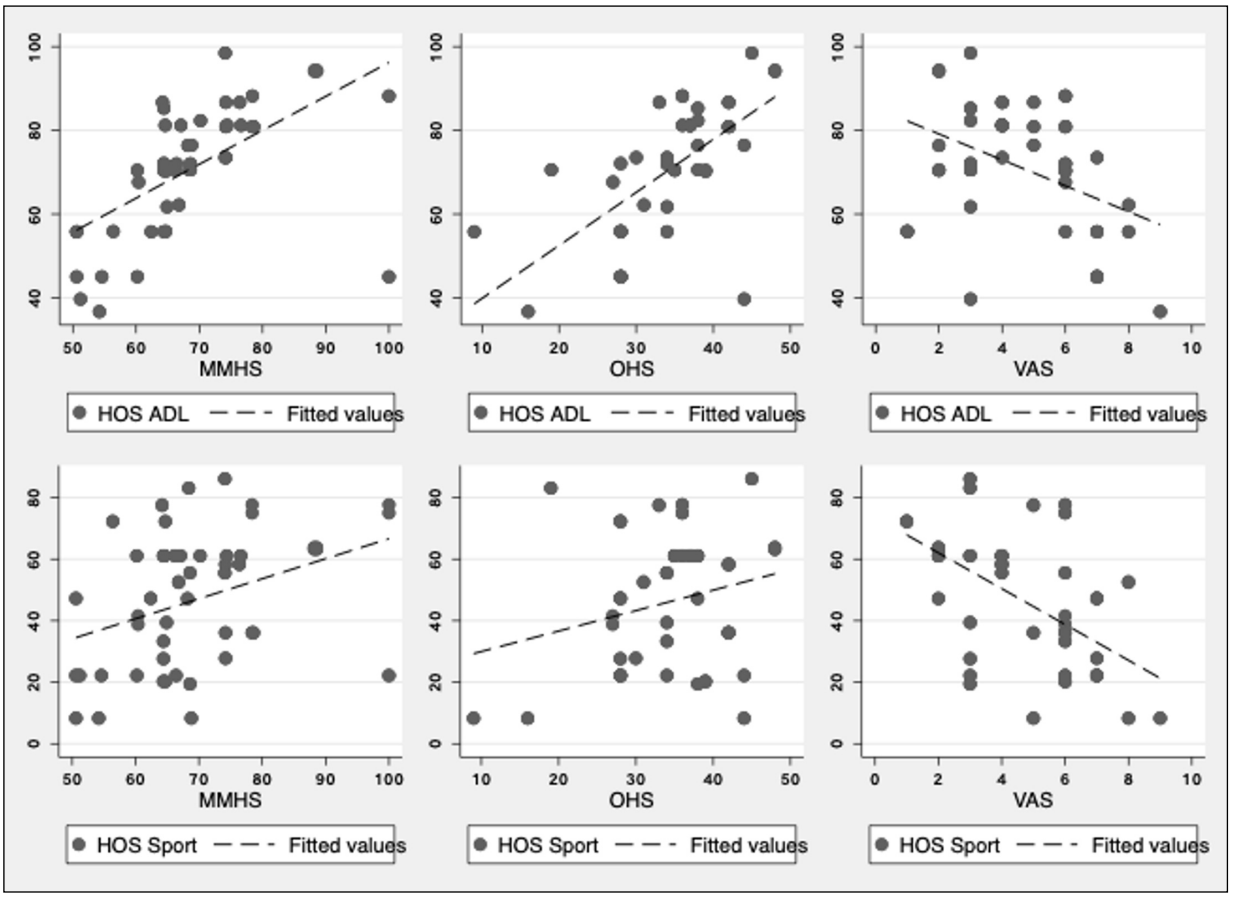

Figure 1. Regression plots. The figure shows three correlation plots for the HOS ADL subscale and three for the HOS Sports subscale with each of the external constructs that have been assessed (MMHS, OHS, and VAS). Correlation analysis showed a positive statistically significant correlation of both HOS subscales with MMHS and OHS and a negative statistically significant correlation with VAS for pain.

Intraclass correlation coefficients were excellent for total HOS (ICC average 0.99, 95% CI: 0.99, 0.99), for ADL subscale (ICC average 0.99, 95% CI: 0.99, 0.99), and for sport subscale (ICC average 0.99, 95% CI: 0.99, 0.99). Details are reported in Table 3. Also, internal consistency analysis showed excellent Cronbach's alpha for the ADL subscale (first series alpha=0.97, second series alpha=0.97) and for the sports subscale (first series alpha=0.96, second series alpha=0.96). Details are summarized in Table 4.

Minimal Detectable Change was 6.22 points for the ADL subscale, 8.77 for the Sports subscale, and 13.4 for the total score. No floor or ceiling effects were found either for the total score or for subscales, with floor and ceiling clusters being all under 15%, as shown in Table 5.

Table 3. Intraclass Correlation Coefficient.

	Ratings	Patients	ICC average	ICC individual	95% CI	
HOS ADL	2	45	.999995	.9999901	.999982	.9999945
HOS Sport	2	45	.9997283	.9994568	.999016	.9997007

HOS: Hip Outcome Score, ADL: Activity of Daily Living, ICC: Intraclass Correlation Coefficient, 95% CI: 95% Confidence Interval.

Table 4. Cronbach's Alpha Internal consistency.

	Alpha reliability coefficient	Item-rest correlation	Item-test correlations	Average interitem correlation
HOS ADL 1	.9676479	.8217029	.87583	.8567741
HOS Sport 1	.9634972	.8620502	.9046899	.8407399
HOS ADL 2	.967666	.8215255	.8757021	.8568452
HOS Sport 2	.9637824	.8592954	.9027338	.8418267

HOS: Hip Outcome Score, ADL: Activity of Daily Living.

Table 5. Floor and ceiling effect.

Score	SEM	MDC	Worst	Best	Freq. W	Freq. B
HOS ADL	2.3227	6.2225133	42.9225133	92.2774867	4.40%	2.20%
HOS Sport	3.274536	8.77248194	17.0724819	77.3275181	6.67%	4.44%

HOS: Hip Outcome Score, ADL: Activity of Daily Living, SEM: Standard Error of Measurement, MDC: Minimal Detectable Change.

DISCUSSION

The main findings of the present study showed a successful cross-cultural adaptation of the HOS to the Italian language. According to internal consistency and reliability analysis, the developed construct showed acceptable psychometric properties in Italian patients affected by FAI. Furthermore, external consistency assessment through correlation analysis showed concordance with a similar construct assessing hip function and pain (MMHS, OHS, and VAS for pain). The absence of missing data reflects the good acceptance of the Italian HOS and a complete understanding of the questions. No floor or ceiling effects were observed according to the findings for pre-operative patients reported in previous studies[7].

In accordance with the original English version of the HOS, reliability was satisfactory[7]. Internal consistency was comparable to that observed in the original version[7,27] and in validation studies[9,10,12] for other languages, with a Cronbach's alpha over 0.9 for both total score and subscales, thus excluding possible redundancy of the items of the OHS questionnaire. As reported in previous transcultural adaptation studies[9], the test-retest reliability was checked with a second pre-operative assessment at two weeks from the first one. This time was considered sufficient to avoid the patient recalling his previous answers, but also not enough for a relevant change in the symptoms and functionality of the hip.

Forward translation of the questionnaire to Italian was carried out without any relevant discordance in versions proposed by the two independent translators, and no concerns were raised by the native English translator for back-translation into English. This was also confirmed by the absence of concerns regarding the meaning of individual items of the questionnaire during the filling of the form by any patient. In previous studies where the transcultural adaptation process was carried out, a transcultural equivalence score was used to check for the goodness of adaptability of the translation to the comprehension of Korean patients[9], while this was not carried out for German[10] and Spanish[12] versions of HOS, where only minimal discrepancies were reported in the translation process. This was probably due to the cultural variability of people outside Europe, especially for the Asian population, for which activities of daily living and lifestyle may be locally different.

External validity analysis showed a concordance of ADL and sport subscales with all external constructs, with a significant correlation of ADL subscale and sport subscale with MMHS, while only ADL subscale correlated significantly with OHS. Inverse concordance was found for both subscales with VAS for pain. These results were in line with previous validation studies[7,9]. In the original validation of the English version of HOS, Martin and Philippon[7] reported Pearson's coefficients above 0.8 in correlating HOS ADL with Short Form 36, and Lee et al[9] reported significant Spearman correlation coefficients between HOS and SF-36 and Hip disability and Osteoarthritis Outcome Score (HOOS), for both subscales.

In the same study, a lower significant correlation was found between the HOS sport and symptoms scale of HOOS (p=0.02), thus suggesting that our findings (i.e., the non-significant regression between HOS sport and OHS) could be explained by the more disability-focused construct of OHS, that may differ from the ability-focused construct of HOS sport subscale. However, in the study conducted for trans-cultural adaptation of HOS in the German language, a positive correlation was found with OHS[10]. Moreover, in graphical analysis conducted by means of regression plots (Figure 1), a positive concordance is shown, though not significant in formal analysis. The wide variability in the use of external constructs within the different adaptation and validation studies is due to the availability of the PROMS for the local language.

Results of internal consistency analysis showed an MDC value of 6.22 points for the ADL subscale, and of 8.77 for the Sports subscale. This finding means that only a change between two subsequent measurements greater than the MDC value can be interpreted with 95% certainty as a real change. These results are quite different from validation studies of the Spanish[12] and Dutch[11] versions of HOS. For the Dutch version, internal consistency was assessed using MCID (reporting higher values) and not MDC; thus, no direct comparison can be made[11]. However, MDC values reported by Seijas et al[12] for the Spanish version were 13.7 points for the ADL subscale and 22.8 points for the Sports subscale. These higher values may reflect a different variance in the series, probably due to a larger population (100 subjects) and higher mean age (45.1 years). However, further studies on larger population samples are being conducted in literature, to define the MDC of the Italian version of HOS, considered as the smallest change in score, perceived as important by patients, clinicians, or relevant others, thus providing a basis in determining clinical significance over and above statistical significance. No floor or ceiling effects were detected, with lower and upper clusters being smaller than 7% of the entire population.

Disease-specific disability scales have become complementary to traditional outcome measures, such as physical or radiographic assessments. The extensive use of hip assessment instruments in international clinical trials and in daily practice requires either the elaboration of new scores or the adaptation and validation of questionnaires already accepted in the scientific community. Concerning hip and groin outcomes, previous attempts to define a reliable PROM were carried out by Dutch surgeons developing the Copenhagen Hip and Groin Outcome Score (HAGOS), also used in national registries[28] and adapted to the Swedish language[29]. However, no further development is available in literature for HAGOS, thus confining the use of this tool to some small populations. The need for multiple-language versions of existing validated questionnaires plays a key role in standardizing the outcome assessment and increasing the statistical power of clinical studies. To date, no questionnaire to measure pain, functional impairment, and health-related quality of life in patients with FAI has been validated in the Italian language. Thus, we recommend the use of the Italian version of HOS for the comparison of outcomes in groups of Italian patients affected by FAI.

Limitations

Some limitations affect the methodological quality of the current investigation. Firstly, only patients from one urban outpatient clinic in Northern Italy were assessed, thus leading to possible selection bias in excluding patients from different regions, especially from rural areas. The relatively small number and younger age of the sample may impact outcomes by reducing variance and thus kurtosis of distributions, which may decrease MDC and increase correlation coefficients and ICC. The multicentric design would embrace a wider population, accounting for possible minimal differences in level of education, socioeconomic condition, and language comprehension. Furthermore, although FAI is a sports-related pathology and HOS is focused on the assessment of sports activities, no specific focus was put on the inclusion of patients with specific sports activity levels using Tegner scale, or sub-analysis was available stratifying results for the level of activity. In addition, responsiveness to treatment for the construct has not been assessed, as the HOS was administered twice before undergoing hip arthroscopy. For this reason, further studies from our group are ongoing.

CONCLUSIONS

The Italian HOS questionnaire is valid and reliable for use in Italian patients undergoing hip arthroscopy for FAI. The present study confirmed the research hypothesis and provided a valid tool for future studies on sports medicine concerning hip pathologies and hip arthroscopy. Future studies on larger samples could be useful in quantifying the clinically relevant measures (i.e., MDC, Minimally Clinical Important Difference and Clinically Meaningful Difference), assessing HOS responsiveness after treatment, and further understanding the relationship between HOS sport subscale and other validated tools in the Italian language.

Conflicts of Interest:
The authors declare no conflict of interest for the present manuscript.

Funding:
No funding was received for conceiving, conducting and reporting the study.

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Data Availability:
Raw data are available upon reasonable request to the corresponding author.

Authors' Contributions:
Manuscript design and data collection (M.P.), study design and formal analysis (G.T.), manuscript drafting and editing (M.P. and G.T.), supervision and editing (R.Z. and G.N.B.).

Ethics Approval:
The ethics approval was waived due to the observational retrospective nature of the study.

Informed Consent:
All patients signed an informed consent to data collection and data usage for research purposes.

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