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Research article

Predictive factors of difficult biliary cannulation: An experience of a tunisian tertiary center

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ABSTRACT

Introduction: Selective biliary cannulation is a prerequisite for a successful endoscopic retrograde cholangiopancreatography (ERCP). However, conventional biliary access can be difficult. The aims of our study were to determine the prevalence of difficult biliary cannulation (DBC) and its associated factors and to describe the efficiency and safety of used standard and advanced cannulation techniques.

Methods: We conducted a single-center retrospective study including all patients with naïve papilla who had an ERCP procedure in Gastroenterology department of Mohamed Taher Maamouri Hospital from June 2019 to December 2021. Efficiency was defined as successful selective deep biliary cannulation. DBC was defined based on the presence of one or more of the European Society of Gastrointestinal Endoscopy (ESGE) criteria (5-5-1): more than five cannulation attempts, more than 5 min before cannulation and more than one accidental passage in the wirsung. Prevalence was measured using ESGE 5-5-1 cutoffs and chinese set cutoffs 15-10-2. Predictors of DBC were sought by univariate and multivariate analysis (SPSS software, p significant if < 0.05).

Results: We included 664 patients (mean age 62 years and sex ratio M/W = 0.8). Main indication for ERCP was choledocholithiasis (67%, n = 442) followed by malignant biliary stenosis (21%, n = 138). Based on ESGE criteria, prevalence of DBC was 42.62% (n = 283). Prevalence was 21.15% when 15-10-2 cutoffs are applied in trainee-involved procedure. Cumulative biliary success rate was 96.46%. Standard cannulation method achieved access in 98.2% while advanced methods permitted success in 92.2% in fistulotomy, 94.1% in papillotomy and 77.3% in transpancreatic sphincterotomy. Independent predictive factors of DBC in multivariate analysis were: Trainee presence OR 1.80 [1.24–2.65], SOD OR 4.71 [1.11–19.88], biliary stenosis found on imaging examinations (OR 2.53 [1.63–3.92], small papilla OR 4.09 [1.82–9.17] and difficult orientation of the papilla OR 14.90 [3.28–67.62].

Conclusion: DBC is a frequent endoscopic situation. Predictors of DBC can be related to trainee involvement in the procedure, anatomical and clinical factors. A thorough understanding of these factors can actively contribute to ERCP management plans.

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) remains one of the most challenging procedures in therapeutic endoscopy. Deep biliary selective cannulation is the pillar for a successful ERCP. However, biliary access can be challenging for experts and novices [1]. In addition, difficult cannulation may result in some cases, to the failure of the whole procedure. European Society of Gastrointestinal Endoscopy (ESGE) defines difficult biliary cannulation (DBC) as the presence of one or more of these criteria: more than five attempts to access the papilla; a duration exceeding 5 min trying cannulation once in contact with the papilla and more than one accidental pancreatic duct cannulation or opacification [2]. The incidence of DBC widely varies from a series to another ranging from 5 % to 49%, with a mean rate of 20% [3, 4]. Several predictive factors of this clinical situation have been identified. They can be related to the operator itself, the anatomy of the papilla, or the indication of the

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ERCP [5]. Recognizing these factors can help identify patients at risk of DBC and thus orient the endoscopist to choose the most appropriate cannulation method.

Several studies have dealt with this topic in Europe, Asia and America. However, to the best of our knowledge, this topic was not addressed in the Middle East and Africa. Therefore, our study aims to determine the prevalence of DBC and its predictive factors. Identifying these risk factors will help make informed contributions in ERCP management plans.

2. Materials and methods

We conducted a descriptive retrospective study including all patients who had ERCP from June 2019 to December 2021 in the Gastroenterology department of Mohamed Taher Maamouri University Hospital Nabeul. We excluded patients with incomplete medical records, a non-naïve papilla, impassable duodenal stenosis or a choledecoduodenal fistula, who had gastric surgery in the past or who presented with diseases affecting the main pancreatic duct: Wirsung stenosis, wirsung lithiasis or divisum pancreas.

In our study we opted for the DBC definition suggested by ESGE: more than five attempts to access the papilla; a duration exceeding 5 min trying cannulation once in contact with the papilla, and more than one accidental pancreatic duct cannulation or opacification [2, 6]. Since our hospital is affiliated to university, we considered using Wang el al. proposed criteria to determine the DBC rate in trainee-involved procedures: more than 15 attempts to access the papilla, more than 10 min before cannulation, and more than two wirsung accidental passages: 15-10-2 [7]. Our study had only one expert endoscopist defined after accomplishing more than 400 ERCPs [8]. Six others were considered non-experimented endoscopists in training. A trainee operator usually starts the procedure. Takeover by the experimented endoscopist started after 5 min of attempting access to the MBD. This time limit was set since more lengthy procedures (>10 min) for a cannulation attempt in endoscopist training are associated with a higher risk of adverse events [9].

All procedures were performed under general anesthesia and fluoroscopic control and after rectal indomethacin for post-ERCP pancreatitis prophylaxis. After reaching the papilla, a standard cannulation method defined by guide-wire assisted technique was firstly performed. In case of DBC or failure to access the bile duct using a standard technique, more advanced methods such as needle-knife fistulotomy or papillotomy, transpancreatic sphincterotomy (TPS) or pancreatic duct stenting were used. In some cases, the procedure was aborted, and a second ERCP attempt was set. We also defined primary cannulation rate as access to the main bile duct (MBD) during the first ERCP attempt while final cannulation rate as biliary access after a second deferred ERCP attempt.

Predictive factors of DBC were sought by uni and multivariate analysis (SPSS software, p significant if < 0.05): potential predictors were related to the patient (age, gender, history of cholecystectomy and comorbidities), the operator (endoscopist experience and trainee involvement), the ERCP indication, data on imaging examination before the procedure (number of stones, MBD dilation diameter and presence of biliary stenosis) and the anatomy (passable duodenal stenosis, location of the papilla and its morphology, a papilla looking downwards or hidden by a fold and presence of peripapillary diverticulum).

We ensured the reproducibility of our study using STROBE guidelines.

Written informed consent was obtained from all patients in the study. Ethical approval was obtained from Mohamed Taher University Hospital ethics committee.

3. Results

A total of 664 patients were included in this study, with a slight feminine predominance (sex-ratio M: F = 0.8) and mean age of 62 years. An experienced operator performed 89% of the procedures. A trainee started the procedure in most cases (N = 385, 58%), supervised by the experienced operator. We identified 275 patients (41%) with a history of cholecystectomy. ERCP indications were various ranging from choledocholithiasis being the main cause (sequential treatment: N = 192 (29%), residual lithiasis: N = 250 (38%)) followed by biliary malignant obstruction (N = 138, 21%) to liver hydatic cyst (LHC) (N = 36, 5%), stenosis of undetermined origin (N = 29, 4%), post cholecystectomy complications (N = 9, 1%) and sphincter of Oddi dysfunction (SOD) (N = 10, 1%). Imaging examinations revealed multiple stones (N = 64), large stone (N = 39), and MBD stenosis (N = 145). When it comes to endoscopic features, a periampullary diverticulum was present in 12% (N = 72). Papilla morphology was normal in 85% (N = 564), small in 7% (N = 46), and invaded by tumor buds in 3% (N = 22). Its location was primarily in D2 (98.5%). The papilla was either ectopic or hidden in the remaining cases by a fold.

The primary cannulation rate in our series was 92.46%, with a cumulative success rate, after the second attempt, of 96.38%. Figure 1 illustrates management of biliary cannulation in our center.

The prevalence of DBC, defined by ESGE criteria [5], was 42.62% (N = 283).

DBC prevalence was variable according to the fixed cutoffs and trainee involvement as shown in Table 1.

Guide-wire cannulation technique was the most used maneuver to access the MBD (N = 517, 77.86%). A second line cannulation method was used in 123 patients (18.52%) alone or combined with other advanced ones.

In terms of efficacy, the standard and advanced methods allowed biliary access in 91.52% of cases. On the other hand, advanced cannulation methods presented a cumulative success rate of 92.2% in fistulotomy, 94.1% in papillotomy, and 77.3% using TPS.

Thirty-two patients with primary cannulation failure were deferred for a second ERCP. The mean time between two attempts was 17 days. The procedure was successful in 81.25% (N = 26). In 18 succeeded cases, an advanced cannulation method already started in the first attempt was finished during the 2nd ERCP attempt.

In bivariate analysis, we obtained nine predictive factors of DBC: trainee presence (OR 1.80; CI95% 1.29–2.5, p = 0.001), pancreatic cancer (OR 2.3; CI95% 1.50–3.50, $p < 0.001$), stenosis of undetermined origin (OR 2.67; CI95% 1.22–5.83, p = 0.013), SOD (OR 4.11; CI95% 4.05–16.13, p = 0.043), papilla location in D3 (OR 2.36; CI95% 2.16–2.58, p = 0.03), papilla hidden by a fold (OR 2.36; CI95% 2.16–2.58, p = 0.03), difficult orientation of the papilla (OR 17.67; CI95% 4.13–75.4, $p < 0.001$) and small papilla (OR 5.40; CI95% 2.65–11.10, $p < 0.001$) (Table 2). On the other hand, cholecystectomy (OR 0.65; CI95% 0.48–0.89, p = 0.008), residual lithiasis (OR 0.53; CI95% 0.38–0.73, $p < 0.001$) and normal papilla morphology (OR 0.47; CI95% 0.31–0.71, $p < 0.001$) were predictive factors of easy cannulation. It is also worth noting that there was a significant decrease in DBC incidence from the beginning of the study in 2019 compared to its end in 2021 as illustrated in Figure 2.

Multivariate analysis showed a direct and independent association between DBC and five factors: Trainee presence (OR 1.80; CI95% 1.24–2.65, p = 0.002), SOD (OR 4.71; CI95% 1.11–19.88, p = 0.035), MBD stenosis found on imaging examinations (OR 2.53; CI95% 1.63–3.92, $p < 0.001$), small papilla (OR 4.09; CI95% 1.82–9.17, p = 0.001) and difficult orientation of the papilla (OR 14.90; CI95% 3.28–67.62, $p < 0.001$).

4. Discussion

The prevalence of DBC highly varies from one series to another. The defining criteria: the number of cannulation attempts, time before cannulation, and a number of accidental pancreatic duct passages, influence this incidence variability. Cutoffs differ based on association to post-ERCP pancreatitis (PEP) occurrence risk [10]. In fact, according to Halttunen J et al, exceeding five papilla cannulation attempts increased PEP risk from 6.1% to 11.9% [6]. This study was a fundamental scientific

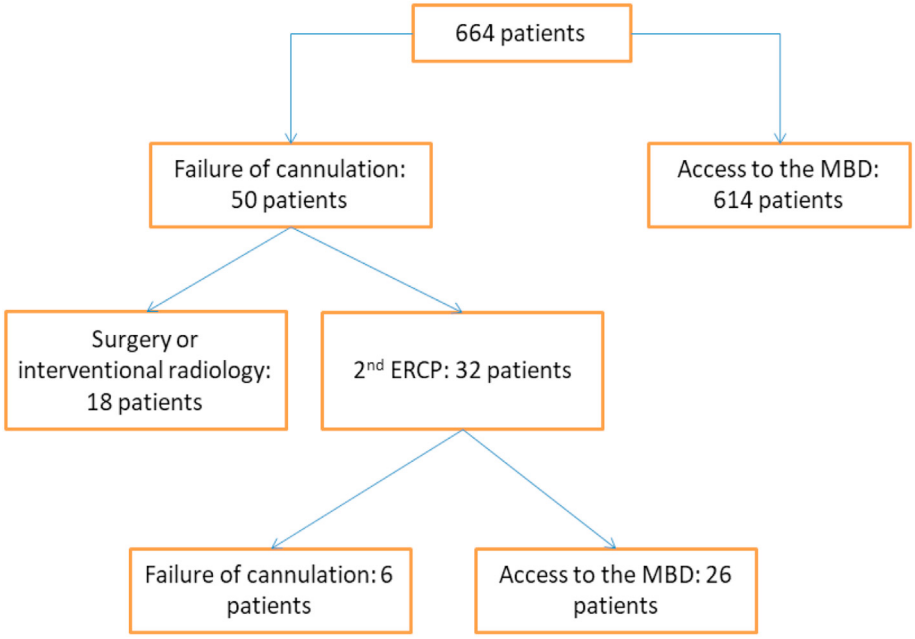

Figure 1. Overview of biliary cannulation. MBD: main bile duct; ERCP: endoscopic retrograde cholangiopancreatography.

Table 1. Difficult cannulation prevalence according to definition and trainee involvement in the procedure.

	5-5-1	15-10-2
DBC prevalence in study population (N = 664)	42.62%	17%
DBC prevalence in trainee involved procedures (N = 383)	-	21.15%
DBC prevalence in non-trainee involved procedures (N = 281)	33.45%	-

paper to build on and set ESGE [5] DBC criteria [2]. ESGE criteria were then validated by Ismail et al [11]. However, it is unclear whether these criteria are convenient for ERCP with trainee involvement.

Since our center is a teaching hospital, we chose to look for DBC incidence in trainee-involved procedures as it might differ from the traditional 5-5-1 criteria. Chinese conducted a large observational case-control study including 4415 participants and concluded that 15-10-2 criteria for DBC could be appropriate in trainee-involved ERCPs [7]. These cutoffs were considered in measuring the prevalence of DBC in our study. In Table 3, the different proposed definitions in literature with their respective DBC incidence.

As shown, prevalence ranged from 4.61% to 49.5%. Our study presents a relatively high incidence of DBC compared to other series when using the ESGE definition. The following reasons can explain this significant incidence. First, our center is a tertiary referral center. Patients with primary cannulation failure are usually addressed for a second attempt in our center. This could create a selection bias. Thus, it could

Table 2. Risk factors of difficult biliary cannulation in bivariate analysis.

		Difficult cannulation N = 283	Easy cannulation N = 381	P	Odds ratio 95% CI
Trainee involvement	Yes	169	174	0.001	1.80 [1.29–2.5]
	No	89	165		
Biliary stenosis on imaging	Yes	79	66	<0.001	2.28 [1.54–3.38]
	No	172	255		
Pancreatic cancer	Yes	64	43	<0.001	2.30 [1.50–3.50]
	No	219	338		
Stenosis of undetermined origin	Yes	19	10	0.013	2.67 [1.22–5.83]
	No	264	371		
Sphincter of Oddi dysfunction	Yes	7	3	0.043	4.11 [1.05–16.13]
	No	276	378		
Papilla in D3	Yes	4	0	0.03	2.36 [2.16–2.58]
	No	279	381		
Papilla hidden by a fold	Yes	4	0	0.03	2.36 [2.16–2.58]
	No	279	381		
Papilla looking downwards	Yes	34	2	<0.001	17.67 [4.13–75.4]
	No	248	379		
Small papilla	Yes	39	13	<0.001	5.40 [2.65–11.10]
	No	244	368		

CI: confidence interval; **D3:** third duodenum.

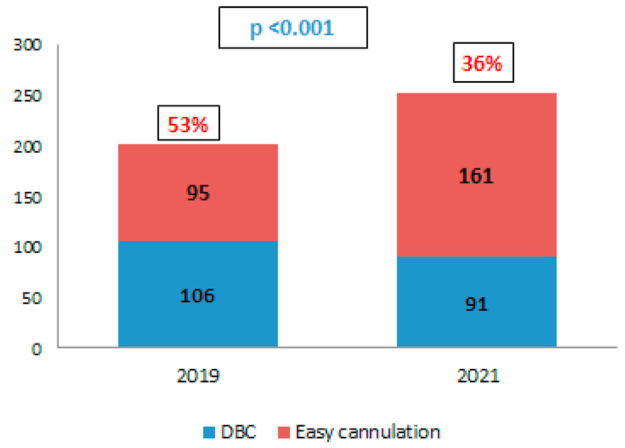

Figure 2. Evolution of difficult cannulation prevalence throughout the years of the study. DBC: difficult biliary cannulation.

Table 3. Review of literature of definitions and prevalence of difficult biliary cannulation.

First author, year	Definition of DBC	Prevalence
Maeda, 2003 [4]	>10 min	53/107 (49.5%)
Ito, 2010 [15]	>5 attempts	108/145 (7.4%)
Lee, 2012 [16]	>10 min	101/1522 (6.6%)
	>5 PD attempts	
	>10 attempts	
Swan, 2013 [13]	>10 min	73/464 (15.7%)
	>10 attempts	
	>4 PD cannulation	
Zang, 2014 [17]	>10 min	164/1181 (13.9%)
	>5 PD cannulation	
Ismail, 2019 [11]	ESGE definition	311/821 (37.9%)
Tabak, 2020 [18]	ESGE definition	209/614 (34.04%)
Cáceres escobar, 2021 [5]	ESGE definition	144/498 (28.9%)
Cankurtaran, 2021 [19]	ESGE definition	97/438 (22.14%)
Flumignan, 2021 [20]	>10 min	238/1024 (23.24%)
	>5 attempts	
	>5 PD cannulation	
Lee, 2022 [21]	Failure to access the MBD using standard techniques	390/8430 (4.62%)
Dalal, 2022 [22]	ESGE definition	471/368 (12.8%)
Our study	**ESGE definition**	**283/664 (42.62%)**
	15-10-2 criteria	**112/664 (17%)**

DBC: Difficult biliary cannulation, **PD:** Pancreatic duct, **ESGE**: European Society of Gastrointestinal Endoscopy.

increase the portion of patients with DBC. Second, according to Wang et al., trainees' involvement increases the overall cannulation time and attempts, defining difficult cannulation parameters [6]. However, most of the studies listed in Table 3, except those of Swan et al. and Tang et al., did not consider trainee involvement influence in biliary cannulation [12, 13]. Wang looked for an appropriate definition of DBC in the ERCP procedure with trainee involvement. There were two groups in his study, including 1596 patients each. The 15-10-2 criteria for difficult cannulation were proposed for trainee-involved cannulation, and the 5-5-1 criteria were suggested for cannulation without trainee involvement. Our DBC rates agreed with Wang's proposed criteria, as shown in Table 4.

Last but not least, institutional funding for advanced materials and equipment availability undoubtedly affects the procedure course and in a way or another DBC rate [14].

The likelihood of DBC is associated with several factors. Table 5 assembles studies with their respective identified risk factors of DBC.

Table 4. Incidence of difficult cannulation using ESGE criteria and Wang proposed criteria.

	Wang et al. [7]	Our study
ESGE criteria in no-trainee group [5]	35.5%	**33.45%**
Wang criteria in the trainee-involved group [10, 11, 12, 13, 14, 15]	31.8%	**21.15%**

ESGE; European Society of Gastrointestinal Endoscopy.

Trainee involvement in ERCP procedures and its impact on the biliary cannulation course is intriguing. This topic has raised some controversy since trainee presence could lengthen the time of the procedure and increase anesthesia and post-ERCP adverse events. However, at least one study in the literature, as shown in Table 5, found an independent association between trainee presence and DBC just like in our study.

On the other hand, a prospective study published in 2017 did not demonstrate a significant association between cannulation rates and learner participation (91% trainee-involved procedure vs. 93% procedures without trainee, $p = 0.8$). Furthermore, the training protocol allowed 6 min of supervised attempts until the expert endoscopist takes over, just like our center protocol [28]. In addition to that, it has been proven that trainees' participation does not increase complication rates [29]. Despite that, a balance should be sustained between training non-experimented endoscopists and securing the safety and success of biliary cannulation.

Five studies listed in Table 5 stated biliary stricture as a predictive factor of DBC. According to Fugazza et al., 56.4% ($N = 351$) of patients with distal malignant biliary obstruction presented a DBC [26].

Based on our results, patients with SOD were considered as predictor of DBC. In this case, the papilla is stenotic and flat, which makes it challenging to access the MBD without multiple attempts [30].

Inversely, our results did not show any association between DBC and choledocholithiasis, particularly multiple stones and large stones, LHC ruptured in the MBD or post-LHC surgery fistula post-cholecystectomy complications.

Coming to anatomical factors, difficult papilla orientation (papilla looking downwards) was an associated factor with DBC in bivariate and multivariate analysis. Looking up to the papilla from below requires a long position scope which is hard to achieve [31, 32].

Several studies listed in Table 5 identified small papilla morphology as a predictive factor of DBC which is coherent with findings in our study; small papilla appeared as a risk factor for DBC in the bivariate and multivariate analysis compared to regular papilla.

Contrary to the literature, we found that patients with cholecystectomy presented easy biliary cannulation. After cholecystectomy, a bile duct dilation of up to 10 mm can be noticed but considered normal [33]. One study revealed that patients with a normal MBD diameter might have a narrower intramural segment making it challenging to catheterize the biliary tract [34]. Conversely, one recent study conducted by Cankurtaran et al. revealed that a history of cholecystectomy was significantly associated with difficult cannulation (OR 2.014, $p = 0.008$) [19]. Another study has shown that ERCP difficulty increases in patients with a history of complicated cholecystectomy [35].

When it comes to salvage methods in the case of DBC, recent literature has proved the superiority of TPS and early needle-knife [36]. Thus, in presence of multiple DBC risk factors, advanced methods should be used early to enhance efficiency and reduce complications rate.

We believe that our study has several strengths. First, identifying different risk factors was based on an exhaustive data collection of an extensive database. Second, our study is the first to determine the prevalence of DBC based on ESGE criteria in our region: Africa and the Arab World. Third, our study sheds light on the importance of identifying risk factors of DBC before or at the beginning of the ERCP procedure and actively contributes to the ERCP planning, allowing necessary measures

Table 5. Literature review of identified risk factors of difficult biliary cannulation.

Author, year	Type of the study and number of included patients	Identified risk factors
Williams, 2012 [23]	Prospective (N = 3209)	- Billroth surgery* - Multiple/large stones* - Old Age - Physical status - Presence of trainee* - Suspected biliary stricture* - Ampullary tumor*
Ismail, 2019 [11]	Prospective (N = 821)	- Biliary stricture
Sabbah, 2020 [24]	Retrospective (N = 181)	- Small papilla - Papilla hidden by a fold - Eccentric papilla
Tabak, 2020 [18]	Prospective (N = 614)	- *Periampullary diverticum* - Ampullary carcinoma - Papillary anatomy
Chen, 2020 [25]	Retrospective (N = 286)	- Small papilla* - Protruding papilla* - Malignant MBD obstruction* - Age*
Cáceres escobar, 2021 [5]	Retrospective (N = 498)	- Gender female - Acute care hospital setting* - Redundant papilla* - Peridiverticular papilla* - Pancreatic cancer
Fugazza, 2021 [26]	Retrospective (N = 622)	- Biliary stenosis
Saito, 2022 [27]	Retrospective (N = 1406)	- Non-expert endoscopist* - Low-volume center* - Absence of cholangitis* - Normal serum bilirubin* - Intradiverticular papilla - Type of major papilla
Our study	**Retrospective (N = 664)**	- **Trainee involvement*** - **Pancreatic cancer** - **Stenosis of undetermined origin** - **Sphincter of Oddi dysfunction*** - **MBD stenosis found in imaging*** - **Ectopic location of the papilla*** - **Small papilla*** - **Difficult orientation of the papilla***

MBD: main bile duct, *: factors appeared in multivariate analysis.

to improve the probability of success. Last but not least, the multivariate analysis allowed us to establish five independent predictive factors of DBC. However, some limitations must be acknowledged. Our study is mono-centric and retrospective. Also, DBC prevalence could be over-estimated in our series. Biliary cannulation was challenging in some cases either because of the lack of materials or frequent crashes of sphincterotomes and guide wires per procedure. Such external factors were not considered in the data analysis. These factors were constantly present during the years of the study but, we did not study to which extent they influenced cannulation difficulty. More studies are warranted in this regard.

5. Conclusion

The predictors of DBC are related to trainee involvement, anatomical and clinical factors. A thorough understanding of these factors can actively contribute to ERCP management plans to access the bile duct safely. In this regard, precision medicine using machine learning and artificial intelligence applied in imaging and endoscopy can offer a significant aid in predicting DBC and assisting endoscopists. Ideally, a risk estimate and scoring system should be created to predict the likelihood of complications related to DBC.

Declarations

Author contribution statement

Khalaf Ben Abdallah: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Lamine Hamzaoui: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Moufida Mahmoudi, Amal Khsiba, Manel Yakoubi and Asma Ben Mohamed: Analyzed and interpreted the data.

Mouna Medhioub and Mohamed Mousaddak Azouz: Performed the experiments; Analyzed and interpreted the data.

Ines Cherif: Contributed reagents, materials, analysis tools or data.

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Data availability statement

Not Applicable.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

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