

Safety and Efficacy Results from a Randomized Controlled Trial Comparing Thulium Fiber Laser and Holmium: YAG Laser Lithotripsy in Mini-Percutaneous Nephrolithotomy

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Abstract

Objective

To compare the safety and efficacy of Thulium fiber laser (TFL) versus Holmium: Yttrium Aluminum Garnet (Ho: YAG) laser lithotripsy in miniaturized percutaneous nephrolithotomy (mini-PCNL).

Materials and Methods

This randomized controlled trial enrolled 180 patients with renal stones 10–30 mm undergoing mini-PCNL. Patients were randomized 1:1 to receive either TFL (n = 90) or Ho: YAG laser lithotripsy (n = 90). The primary outcomes were *stone disintegration time* and *stone-free rate*. Secondary outcomes included operative time, complications, hospital stay, and blood loss.

Results

Mean stone disintegration time was significantly shorter with TFL than Ho: YAG (11.25 ± 1.10 vs. 18.19 ± 2.54 minutes, $p < 0.001$). Stone-free rates were better in the TFL group (96.7% TFL vs. 84.4% Ho: YAG, $p = 0.005$). Mean operative time was reduced in the TFL group (50.00 ± 4.82 vs. 57.69 ± 4.92 minutes, $p < 0.001$). Overall complication rates were similar between groups. However, the Hemoglobin drop was more in the TFL group (1.03 vs. 0.80, $p = 0.048$).

Conclusions

TFL demonstrated significantly *higher efficacy for stone disintegration time and stone-free rates* while maintaining a comparable overall safety profile.

Introduction

Urinary stone disease (urolithiasis) has become a global health burden with a steadily increasing incidence worldwide. While open stone surgery was historically the primary definitive treatment option, recent decades have seen a significant shift toward minimally invasive interventions, including Shock Wave Lithotripsy (SWL), ureterorenoscopy (URS), and Percutaneous Nephrolithotomy (PCNL) (1, 2). The choice of treatment is captured in different algorithms driven by patient characteristics, renal anatomy, and stone characteristics (Fig. 1).

PCNL remains the reference standard treatment for larger renal calculi (3, 4). While the technology has matured, more recently miniaturization has led to the development of techniques that utilize smaller access tracts (14–20 Fr) aimed at reducing morbidity while maintaining efficacy (5, 6). These minimally

invasive approaches have demonstrated comparable stone clearance rates to standard PCNL at reduced bleeding, shorter hospital stays, and lower complication rates (7, 8).

Stone disintegration can be accomplished by different devices including pneumatic lithotripters, ultrasonic probes and laser devices. The latter are available using different energy sources and laser fibers. The question often raised is which laser device is preferential. For over two decades, Holmium: yttrium aluminum garnet (Ho:YAG) laser has been the reference standard for intracorporeal laser lithotripsy (9, 10). Despite its proven efficacy, Ho:YAG laser has inherent limitations, including large laser device size, limited ability to achieve high frequencies, and significant stone retropulsion during fragmentation (9, 11). The recently introduced thulium fiber laser (TFL) offers potential advantages over traditional Ho:YAG systems, including higher ablation efficiency, reduced retropulsion, and improved visibility during lithotripsy. (6, 12–14)

In vitro studies have demonstrated that TFL produces two to four times higher ablation rates than the Ho:YAG laser (9, 15). Clinical studies in ureteroscopy have shown promising results with TFL, demonstrating shorter operative times and improved stone-free rates. However, limited data exist comparing TFL and Ho:YAG laser specifically in the context of mini-PCNL procedures.

The primary objective of the present study is to evaluate the efficacy of TFL versus Ho:YAG laser lithotripsy prospectively in patients undergoing mini-PCNL for renal calculi. The secondary objective is to study and compare the safety of both lasers.

Materials and Methods

This prospective, single-blinded, randomized controlled trial was conducted upon receiving approval from the Institutional Ethics Committee **EC/NEW/INST/2022/KN0042**. Written informed consent was obtained from all participants prior to enrolment. The trial was registered with the **Clinical Trial Registry of India (CTRI/2024/06/068616)**.

Consecutive patients aged 18–75 years with renal calculi measuring 10–30 mm on computed tomography (CT) scan who were candidates for mini-PCNL were considered for enrolment. Patients were enrolled when renal function was normal (Serum creatinine < 2.0 mg/dl) and in the absence of an active UTI, after written informed consent.

Pregnant women, patients with bleeding disorders, with solitary kidneys or kidney anomalies that preclude percutaneous access, and those with previous ipsilateral percutaneous procedures were excluded.

Patients were randomized by computer in a 1:1 ratio to receive either TFL or Ho:YAG laser lithotripsy. Randomization was performed using an online randomizer tool (www.randomizer.org). Given the nature of the intervention, the surgeon could not be blinded to the treatment allocation; however, the study subjects were blinded.

Urologists with experience > 100 mini-PCNL cases performed all procedures. After general anesthesia and prone positioning, access was obtained using the bull's-eye technique under fluoroscopic guidance. The tract was dilated to 15/18Fr using a 12Fr Nephroscope (Wolff, Germany).

In the TFL Group, stone fragmentation was performed using a 60W thulium fiber laser system (Urolase-SP, IPG Photonics, Russia) with a 365µm fiber. Settings ranged from 1.0-1.5J energy and 6-15Hz frequency, with total power of 6-15watts in fragmentation mode. (9, 11)

In the Ho:YAG Group, stone fragmentation was performed using a 35W holmium laser system (Litho-35W, Quanta Systems, Italy) with a 365µm fiber. Settings ranged from 0.8-1.2J energy and 10-15Hz frequency, with 8-18watts power levels in fragmentation mode. (9, 11).

Stone fragments were evacuated using the whirlpool/vortex effect, while larger fragments were removed with a fine stone grasper. Complete stone clearance was confirmed by nephroscopy and fluoroscopy. Double-J stents were placed in all patients, with percutaneous nephrodrain if warranted.

Primary Outcomes:

Stone disintegration time and Stone free rates

Secondary Outcomes included:

Total operative time (skin puncture to procedure completion),

Perioperative complications (Clavien-Dindo classification),

Hospital length of stay,

Hemoglobin drop,

Blood transfusion requirement, and

Stone-free rate at 2–4 weeks and 3 months post-procedure

Stone disintegration time was measured from the initial laser activation to complete stone fragmentation.

Operative time was measured from initial puncture to completion of the procedure.

Stone-free status was defined as the absence of residual fragments < 4 mm on NCCT at 2–4 weeks before stent removal and at 3-month follow-up (16). NCCT KUB was reconstructed with a slice thickness of 1-2mm. The residual stone fragments were graded into groups of no residue, <2mm, 2-4mm, and >4mm fragments.

The operating surgeon was asked to assess the endoscopic vision during lasing and mark it on a Likert scale from 1 to 3, corresponding to excellent vision to blurred vision. (17)

Stone retropulsion was also assessed with a Likert scale from 1 to 2, where 1 represented no retropulsion and 2 represented retropulsion. (17)

Ease of procedure was also assessed with a Likert scale from 1 to 3, where 1 represented an easy level difficulty with no retropulsion and no vision change while using the laser, 2 represented medium level difficulty with mild retropulsion but allowed easy lasing and mild haziness and cloudiness on lasing, and 3 represented hard level difficulty, severe retropulsion, and blurred vision on lasing. (17)

Statistical Analysis

The sample size calculation was based on the primary outcome of stone disintegration time.

Total sample size = $2n$

$$n = \frac{2(Z_{\alpha} + Z_{\beta}/2)^2}{(d/\sigma)^2}$$

n is the number of subjects per group

d is the clinically significant difference in mean

$Z_{\alpha} = 1.96$ for 5% level of significance

$Z_{\beta} = 0.84$ for 80% power, $d/\sigma = 0.5$, i.e., Moderate effect size.

Statistical analysis was performed using SPSS version 26.0. Continuous variables were presented as mean $\pm$ standard deviation and compared using independent t-tests or Mann-Whitney U-tests as appropriate. Categorical variables were presented as frequencies and percentages and compared using chi-square or Fisher's exact tests. A p-value < 0.05 was considered statistically significant. Analysis was performed on an intention-to-treat basis.

Results

From June 2024 to June 2025, a total of 198 patients were enrolled, meeting the inclusion criteria, 180 randomized patients completed the study and were included in Intention to treat. Patient flow through the study is shown in Fig. 1. Baseline characteristics were well matched across groups (Table 1). The mean age was 40.8 ± 14.6 years, with 68% of patients were male. Mean stone size was 16.3 ± 4.0 mm, with comparable stone volume and density between groups.

Table 1
Baseline Patient and Stone Characteristics

Parameters	Laser Used		p value
	Ho:YAG (n = 90)	TFL (n = 90)	
Age (Years)	47.59 ± 12.86	49.03 ± 12.29	0.442 ¹
Gender			0.523 ²
Male	63 (70.0%)	59 (65.6%)	
Female	27 (30.0%)	31 (34.4%)	
Stone Side			0.881 ²
Left	41 (45.6%)	42 (46.7%)	
Right	49 (54.4%)	48 (53.3%)	
Stone Size Length (mm)	16.11 ± 4.32	16.18 ± 3.77	0.808 ³
Stone Size Width (mm)	14.28 ± 3.60	14.62 ± 3.52	0.617 ³
Stone Size Height (mm)	13.94 ± 3.88	13.36 ± 3.29	0.541 ³
S.T.O.N.E. Nephrolithometry Size (mm ²) (Length x width)	239.49 ± 111.68	243.20 ± 97.82	0.550 ³
Stone Volume (mm ³)	3455.48 ± 1999.74	3402.43 ± 1917.43	0.950 ³
Stone Density (HU)	1007.41 ± 312.27	1091.09 ± 313.58	0.075 ¹

Table 2
Intra-operative Outcomes

Parameters	Laser Used		p value
	Ho:YAG (n = 90)	TFL (n = 90)	
Access ***			0.006 ²
Infracostal	60 (66.7%)	76 (84.4%)	
Supracostal	30 (33.3%)	14 (15.6%)	
Access Type			0.289 ²
IC	43 (47.8%)	53 (58.9%)	
MC	19 (21.1%)	17 (18.9%)	
SC	28 (31.1%)	20 (22.2%)	
Dilatation Method			0.733 ²
15Fr	24 (26.7%)	22 (24.4%)	
18Fr	66 (73.3%)	68 (75.6%)	
Length of Tract (cm)	9.17 ± 1.25	9.02 ± 1.16	0.338 ³
Energy Used (kJ) ***	10.75 ± 1.23	9.01 ± 0.92	< 0.001 ³
Lasing Time (minutes) ***	18.19 ± 2.54	11.25 ± 1.10	< 0.001 ³
Visibility ***			0.014 ⁴
No Changes in Visibility	65 (72.2%)	74 (82.2%)	
Little Haziness and Cloudiness	18 (20.0%)	16 (17.8%)	
Severe Haziness and Cloudiness	7 (7.8%)	0 (0.0%)	
Stone Retropulsion Rate ***			< 0.001 ²
No Retropulsion	38 (42.2%)	75 (83.3%)	
Retropulsion	52 (57.8%)	15 (16.7%)	
Ease of Procedure ***			< 0.001 ⁴
Easy	33 (36.7%)	67 (74.4%)	
Medium	49 (54.4%)	23 (25.6%)	

Parameters	Laser Used		p value
	Ho:YAG (n = 90)	TFL (n = 90)	
Hard	8 (8.9%)	0 (0.0%)	
Duration of Surgery (minutes) ***	57.69 ± 4.92	50.00 ± 4.82	< 0.001 ³

The TFL group demonstrated significantly shorter stone disintegration time compared to the Ho:YAG group (11.25 ± 1.10 vs. 18.19 ± 2.54 minutes, $p < 0.001$), representing a 38% reduction in fragmentation time. (Mean stone disintegration time difference = 6.94 minutes, $p < 0.001$)

Mean operative time was significantly shorter in the TFL group (50.00 ± 4.82 vs. 57.69 ± 4.92 minutes, $p < 0.001$), representing a 14% reduction in total procedure duration. (Mean difference in operative times = 7.69 minutes, $p < 0.001$)

NCCT KUBs done post-procedure were reconstructed with 1-2mm slice thickness and grouped into 4 groups. (Table 3).

Table 3. Stone-free Outcomes

Parameters	Laser Used		p value
	Ho:YAG (n = 90)	TFL (n = 90)	
Stone-Free Rate based on NCCT KUB at 2-4 weeks post procedure at stent removal (Yes)***	76 (84.4%)	87 (96.7%)	0.005 ²
Stone-Free Rate based on NCCT KUB at 3 months post procedure on follow-up (Yes)***	82 (91.1%)	89 (98.89%)	0.005 ²

At 2-4 weeks:

Stone Residue	Ho: YAG group	TFL group	p-value
No residue	55	75	0.005
<2mm	9	7	
2-4mm	12	5	
>4mm	14	3	

At 3 months:

Stone Residue	Ho: YAG group	TFL group	p-value
No residue	70	84	0.005
<2mm	5	3	
2-4mm	7	2	
>4mm	8	1	

At 2–4 weeks & 3 months of post-procedure on follow-up, NCCT KUB was done and stone-free rates were assessed, which were better in the TFL group (96.7% TFL vs. 84.4% Ho: YAG, $p = 0.005$) & (98.89% TFL vs. 91.1% Ho: YAG, $p = 0.005$), respectively.

Overall complication rates were similar between groups. However, the Hemoglobin drop was more in the TFL group (1.03 vs. 0.80, $p = 0.048$). All cases of haematuria were self-limiting, and most were managed conservatively, except for 2 patients who required sheath washes for clot evacuation.

Mean hospital stay was comparable between groups (2.6 ± 0.8 vs. 2.8 ± 0.9 days, $p = 0.234$). Most patients in both groups (92%) had hospital stays of 2–3 days. (Table 4)

Table 4. Complications

Parameters	Laser Used		p value
	Ho:YAG (n = 90)	TFL (n = 90)	
Clavien-Dindo Classification ***			0.022 ⁴
I	31 (34.4%)	48 (53.3%)	
II	56 (62.2%)	38 (42.2%)	
IIIA	3 (3.3%)	4 (4.4%)	
IIIB	0 (0.0%)	0 (0.0%)	
IV	0 (0.0%)	0 (0.0%)	
Change in Haemoglobin (g/dL) ***	-0.80 $\pm$ 0.82	-1.03 $\pm$ 0.92	0.048 ³
Change in Total Leukocyte Count (cells/μL)	4.04 $\pm$ 5.35	4.60 $\pm$ 5.02	0.419 ³
Change in Urea (mg/dL)	4.22 $\pm$ 8.86	5.44 $\pm$ 7.28	0.547 ³
Change in Creatinine (mg/dL)	0.16 $\pm$ 0.27	0.21 $\pm$ 0.20	0.118 ³

Discussion

The findings highlight TFL's potential advantages in stone-free rates (SFR), operative efficiency, and intraoperative characteristics, alongside a nuanced safety profile with increased minor bleeding risks.

The present study confirms that *TFL is associated with a higher SFR for renal stones than Ho:YAG* (odds ratio [OR] 3.14, 95% CI: 1.69–5.86; $p < 0.001$). This advantage may be attributed to TFL's ability to operate at higher pulse frequencies (up to 1000 Hz) and produce finer stone fragments through dusting techniques, facilitating easier clearance through smaller access sheaths used in Mini-PCNL (19, 20). TFL's lower pulse energy (0.2–0.4J) compared to Ho:YAG (0.5–2J) results in less stone displacement, enhancing procedural efficiency (22). This efficiency is particularly valuable in Mini-PCNL, where smaller sheaths (15–18 Fr) require precise fragmentation to avoid clogging or prolonged procedures.

Analysis comparing TFL to standard Ho:YAG (without pulse modulation like MOSES) showed an SFR advantage for TFL. This suggests that TFL's efficacy may be more pronounced than that of older Ho:YAG systems, whereas advanced Ho:YAG technologies may narrow the gap. (21)

TFL exhibited significantly less stone retropulsion (16.7% vs. 57.8%, $p < 0.001$) and better visibility (0% vs. 7.8% severe haziness, $p = 0.014$) compared to Ho:YAG. Stone retropulsion, a common challenge in Ho:YAG lithotripsy due to its higher pulse energy, can complicate procedures by requiring repositioning of the laser fiber or stone.

TFL's reduced retropulsion is supported by an in vitro study, which found TFL produced 50–70% less retropulsion than Ho:YAG at comparable energy settings (22). Improved visibility with TFL, with no cases of severe haziness, likely stems from its finer dusting effect, which produces less debris and maintains a clearer operative field. This is critical in Mini-PCNL, where a limited sheath size can exacerbate visibility issues. TFL's wavelength (1940 nm) has a higher water absorption coefficient, leading to more efficient energy delivery and less cloudiness compared to Ho:YAG's 2100nm wavelength (19).

The study found TFL procedures were rated as easier (74.4% easy vs. 36.7% for Ho:YAG, $p < 0.001$), with no cases classified as hard, unlike Ho:YAG (8.9% hard). This subjective measure reflects TFL's technical advantages, such as reduced retropulsion and better visibility, which simplify intraoperative navigation.

TFL has ease of use in complex cases, such as simultaneous PCNL and endopyelotomy, attributing it to precise energy delivery and minimal tissue disruption (23). However, surgeons' experience and familiarity with TFL's settings may influence perceived ease, suggesting a learning curve that warrants further investigation.

A notable finding was TFL's association with a greater haemoglobin drop. Most cases of persistent haematuria were managed conservatively; only 2 patients required admission for bladder wash (2 cases, 100% in the TFL group). The increased bleeding risk may be related to TFL's 1940nm wavelength, which has higher water absorption than Ho:YAG's 2100nm, potentially causing greater thermal effects on surrounding tissues.

This aligns with reported higher incidence of prolonged postoperative haematuria with TFL (22% vs. 3%, $p = 0.002$), though most cases were self-limiting and managed conservatively (20).

An ex vivo study found that TFL produced deeper incisions in soft tissue at higher energy settings ($\geq 1\text{ J}$), suggesting a potential for increased vascular injury (24).

However, in the in vivo porcine model, no significant difference in urothelial damage between TFL and Ho:YAG when using low power settings ($\leq 20\text{ W}$ in the kidney, $\leq 12\text{ W}$ in the ureter) with continuous irrigation was noted (25, 26). This suggests that bleeding risks can be mitigated with optimized settings and irrigation techniques.

The Clavien-Dindo classification revealed a significant difference in complication distribution ($p = 0.022$), with TFL associated with more Grade I complications (53.3% vs. 34.4%) and fewer Grade II complications (42.2% vs. 62.2%). This indicates TFL may result in more minor, self-limiting complications (e.g., transient haematuria) but fewer complications requiring significant intervention (e.g., antibiotics for fever). Notably, no complications exceeded Grade IIIA in either group, suggesting both lasers are safe for Mini-PCNL.

Ureteroscopic lithotripsy found no significant difference in overall complication rates between TFL and Ho:YAG (RR 0.89, 95% CI 0.65–1.22), indicating that the increased bleeding risk may be specific to Mini-PCNL's direct renal access, which increases vascular exposure (7).

To address bleeding risks, optimizing TFL settings is critical. Settings of 0.2J and 125–200Hz, optimal for dusting and simultaneous aspiration, reducing tissue damage and improving visibility, have been reported (27).

Similar settings (0.2–0.4J, 100–200Hz) for renal stone dusting, noting that lower energy minimizes thermal injury while high frequency maintains fragmentation efficiency, were found effective (28).

Continuous irrigation is also essential to dissipate heat and clear debris, reducing the risk of haematuria (25). These findings suggest that clinicians should prioritize low-energy, high-frequency settings and ensure adequate irrigation to balance TFL's efficacy and safety.

TFL's advantages make it a promising tool for Mini-PCNL, particularly for patients with renal calculi between 1–3cm, where Mini-PCNL offers reduced bleeding and comparable SFR to standard PCNL (29). TFL's reduced retropulsion, fragmenting, and dusting capabilities are especially beneficial for complex or large-volume stones. However, patients with bleeding diatheses, complex renal anatomy, or risk factors for haemorrhage (e.g., anticoagulant use) may require cautious consideration. In such cases, Ho:YAG, particularly with advanced technologies like MOSES, may be preferred, with comparable SFR (78.43% vs. 68.63%, $p = 0.18$) and lower bleeding risks with MOSES-enabled Ho:YAG (30).

The adoption of TFL in clinical practice must also consider cost and accessibility. TFL systems are generally more expensive than Ho:YAG systems, and their maintenance costs may be higher due to fiber

durability concerns.

TFL's shorter operative times and higher SFR could offset initial costs in high-volume centers, but data on long-term economic benefits remain limited (31). Hospitals must weigh these factors against the potential for improved patient outcomes when integrating TFL into their endourology suites.

This study has several limitations that contextualize its findings.

The study's single-center design may limit generalizability to diverse patient populations or surgical settings with varying levels of expertise.

The study did not account for differences in stone composition (e.g., calcium oxalate vs. uric acid), which can also influence fragmentation efficiency. Also, specific TFL and Ho:YAG settings were not detailed, potentially affecting reproducibility. Variability in settings (e.g., pulse energy and frequency) can significantly affect outcomes.

While adequate for detecting differences in SFR, the sample size ($n = 180$) may be underpowered to assess rare complications, such as severe bleeding or Grade IIIB–V Clavien-Dindo events. Finally, the study's follow-up was limited to immediate postoperative outcomes, lacking long-term data on stone recurrence or renal function, which are critical for assessing Mini-PCNL's overall impact.

Conclusion

This RCT demonstrates that TFL offers significant advantages in Mini-PCNL, including higher SFR, shorter operative times, reduced stone retropulsion, better visibility, and greater ease of procedure compared to Ho:YAG. These benefits are likely driven by TFL's technical properties, such as higher pulse frequency and finer dusting capabilities. However, the increased risk of minor bleeding, particularly haematuria, and a greater hemoglobin drop highlight the need for careful patient selection, optimized laser settings, and adequate irrigation to mitigate risks. While both lasers are safe and effective, TFL's efficiency makes it a promising tool for Mini-PCNL, particularly for complex or large-volume stones. However, its adoption should be balanced against cost, surgeon experience, and patient-specific factors.

Abbreviations

TFL

Thulium Fiber Laser

Ho: YAG laser

Holmium: Yttrium Aluminium Garnet laser

PCNL

Percutaneous Nephrolithotomy

Mini

PCNL-Miniaturised PCNL

CT
Computed tomography
UTI
Urinary tract infection
NCCT
Non-contrast CT
KUB
Kidney, ureter, Bladder
SFR
Stone free rate
OR
Odds ratio
RR
Relative risk
RCT
Randomized controlled trial

Declarations

Ethical Compliance

The study was approved by the **Institutional Ethics Committee of Kasturba Medical College & Hospital, MAHE (EC/NEW/INST/2022/KA/0042)**, IEC1: 290/2023, and registered with the **Clinical Trials Registry-India (CTRI/2024/06/068616)**.

All procedures were performed in accordance with institutional and national research committee standards and the 1964 Helsinki Declaration with later amendments.

Author Contributions:

Srinadh conceived the study, collected data, performed statistical analysis, and drafted the manuscript. Sunil Pillai contributed to the study design, supervised the project, and critically revised the manuscript. Arun Chawla assisted with methodology and data interpretation. Padmaraj Hegde provided overall project administration and gave final approval of the version to be published. Chaitanya & Gautam contributed to data acquisition, literature review, and manuscript editing. Jean de la Rosette and Pilar Laguna critically reviewed the manuscript.

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Conflict of Interest:

The authors declare no competing interests.

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Figures



Figure 1

Guidelines for Stone management (EAU Guidelines 2026 for Urolithiasis)

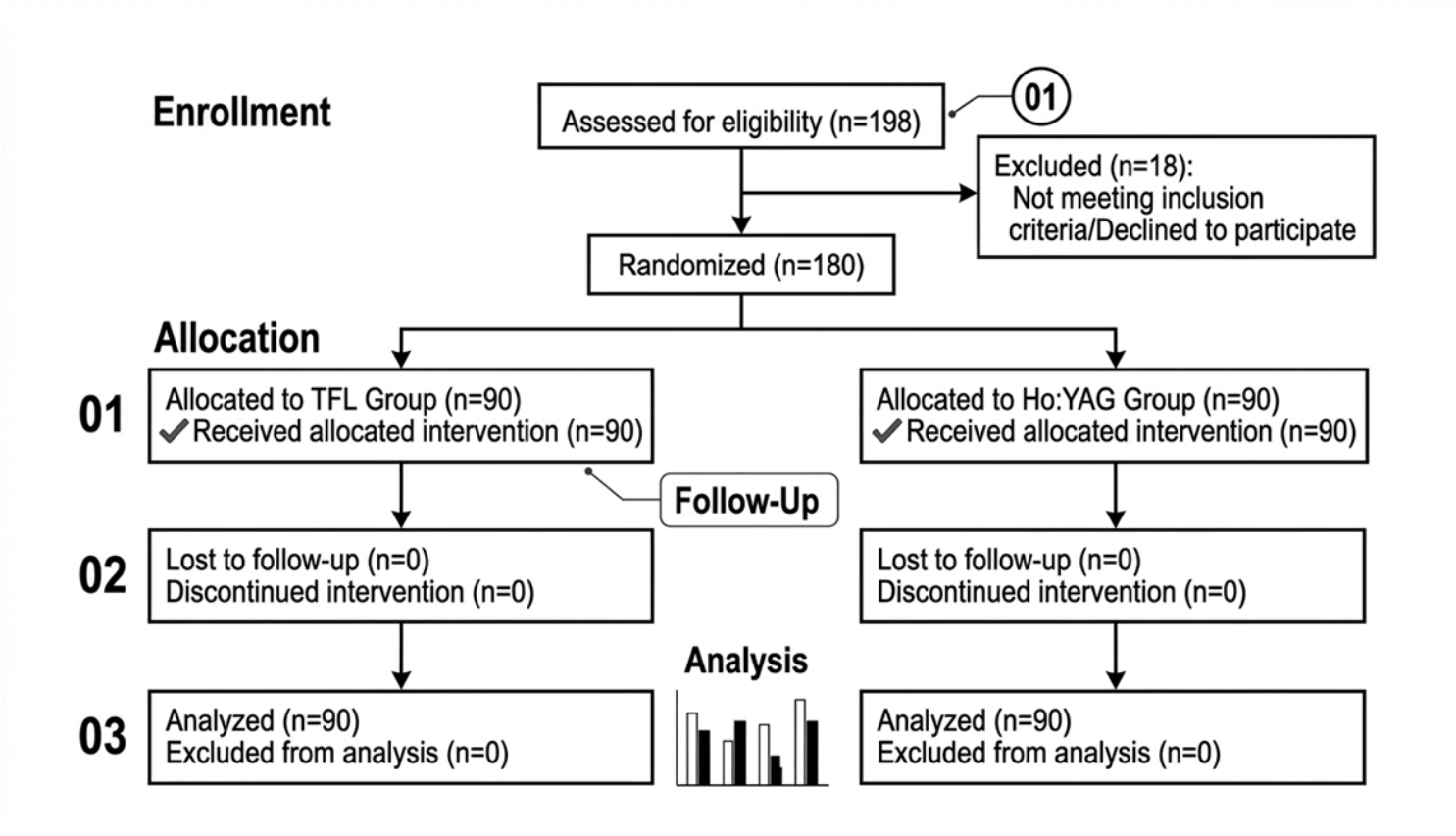


Figure 2

CONSORT Flowchart