Study Document Cover Page

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Comparative Efficacy of Tamsulosin and Solifenacin in Managing Double J Stent-Related Symptoms: A Randomized Clinical Study Using the USSQ Tool

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SYNOPSIS

ON

COMPARISION BETWEEN TAMSULOSIN (ALPHA BLOCKER) AND SOLIFENACIN (ANTICHOLINERGIC IN PATIENTS WITH DOUBLE J STENT – RANDOMIZED COMPARATIVE STUDY

Presented By

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KARACHI

TITLE:

COMPARISION BETWEEN TAMSULOSIN (ALPHA BLOCKER) AND SOLIFENACIN (ANTICHOLINERGIC IN PATIENTS WITH DOUBLE J STENT – RANDOMIZED COMPARATIVE STUDY

INTRODUCTION

Ureteral stents, which were introduced by Zimskind et al in 1967, are widely used for urinary tract disease [1]. Ureteral stents preserve urine flow from the kidney to the bladder in cases of ureteral obstruction (intrinsic or extrinsic). In patients with obvious ureteral obstruction, the placement of a ureteral stent will restart urine transport and protect the kidney from possible risks. The stents also prevent urine extravasation after an operation or trauma[2].

The double-J stent, which is the most common form of ureteral stent, is used in obstructive pyelonephritis, intolerable acute renal colic, ureteral edema, ureter perforation following endoscopic procedures, and with steinstrasse seen after Extracorporeal shockwave lithotripsy (ESWL)[3]. However, despite its usefulness, indwelling stents are often accompanied by significant morbidity, like infectious, stent encrustation, forgotten stent to mild-severe symptoms.

Specifically, DJ stent-related symptoms are urinary frequency (50–60%), sexual dysfunction (male, 42–82% and female, 30–86%), reduced work capacity (58%), urgency (57–60%), dysuria (40%), flank pain (19–32%), incomplete emptying (76%), suprapubic pain (30%), hematuria (25%), and reduced quality of life (QOL) in approximately 80% of the patients[4]. It is reported that an important factor of stent-related symptoms is the pressure transmitted to the renal pelvis during voiding and trigonal irritation by the intravesicular part of the stent[5]. For this reason, several attempts to minimize stent-related symptoms have recently been reported. Pharmacologic management is one such trial[6]. Symptoms of stent discomfort, including bladder irritation symptoms and flank pain or discomfort, are

generally treated with oral analgesics, such as narcotics and anti-inflammatory medications; however these medications are only moderately effective.

Alpha-blockers alleviate bladder irritation due to stents, resulting in reduced incidence of dysuria, frequency, and pain compared to placebo[7]. Additionally, solifenacin anticholinergic has also showed significant benefits in lower urinary tract symptoms, stent-related pain and hematuria[8].

RATIONALE:

A comparison between taking either an alpha-blocker (tamsulosin) or an anti-cholinergic (solifenacin) to alleviate ureteral stent-related symptoms after patients have undergone Dj stenting prior to Extracorporeal shockwave lithotripsy (ESWL), Ureteroscopy (URS) with DJ stent placement or Percutaneous nephrolithotomy (PCNL) with DJ stent placement has not yet been done in Pakistan.

OBJECTIVE:

In this study, we will assess the comparison between an alpha-blocker (tamsulosin) and an anti-cholinergic (solifenacin) in the treatment of ureteral stent-related symptoms using the Ureteral Stent Symptom Questionnaire (USSQ).

OPERATIONAL DEFINITIONS:

Extra corporeal shockwave lithotripsy: A procedure that utilizes shockwaves to fragment kidney stones that can then pass through the urinary tract and be removed.

DJ Stent: A double-J stent is a ureteral stent with curving ends that prevent the stent slipping into the bladder or the kidney and allows continuous drainage of urine into the bladder.

Lower Urinary Tract Sysmptoms: Lower urinary tract symptoms (LUTS) include voiding or storage symptoms such as:-

Hesitancy; Difficulty starting or maintaining a urine stream

Poor and intermittent stream; Intermittent urination is usually a sign of significant underlying bladder problem, most often incomplete bladder emptying can predispose to urinary tract infections, bladder stone formation, and renal insufficiency (damage to the kidneys).

Incomplete bladder emptying; Incomplete bladder emptying occurs when the muscles of the bladder are not able to squeeze properly to empty the bladder.

Frequency; Its normal and how many times is too frequent to urinate.

Urgency; Urinary urgency occurs when the pressure in the bladder builds suddenly, and it becomes difficult to hold in the urine.

Nocturia; the need for patients to get up at night on a regular basis to urinate

Alpha Blockers: Alpha blockers are also known as α-blockers or α-adrenoreceptor antagonists, are a class of pharmacological agents that act as antagonists on α-adrenergic receptors.

Anticholinergic: Anticholinergic drugs block the action of a neurotransmitter called acetylcholine. This inhibits nerve impulses responsible for involuntary muscle movements and various bodily functions. These drugs can treat a variety of conditions, from overactive bladder to chronic obstructive pulmonary disorder.

USSQ: Ureteral Stent Symptoms Questionnaire; a psychometrically valid measure to evaluate symptoms and impact on quality of life of ureteral stents.

HYPOTHESIS:

Solifenacin group have better outcome in comparison to Tamsulosin.

MATERIAL AND METHODS:

Study Design: Comparative study

Setting: Study will be conducted Department of Urology, Liaquat National Hospital Karachi. It will include the patients who had have complaints voiding symptoms like increased urinary frequency, urgency dysuria, incomplete bladder emptying and supra pubic pain.

Study Duration: 6 months after approval of synopsis.

Sampling Technique: non-probability consecutive sampling.

Sample size: The sample size is calculated by using the mean±SD of USSQ score i.e. 76±8 in tamsulosin group and 61±8.8 in solefinacin group. Open Epi Software is used for sample size calculation by taking power of test = 90% and confidence interval 95%, the total calculated sample is 14 patients (7 in each group). To improve the power the study, we will have 30 patients in each group.

Sample selection:

Inclusion criteria:

- Between the ages of 20 and 50 years,
- Patients who consented for unilateral DJ stent placement to relieve upper urinary tract obstruction caused by ureteric calculi or after ureteroscopic lithotripsy for ureteral calculi

Exclusion criteria:

- Having a history of LUTS before DJ stent placement
- Patients with bilateral DJ stent placement.
- Produced Stent related complications (displacement of stent)

DATA COLLECTION PROCEDURE:

Patients fulfilling the inclusion criteria presenting via outpatient clinic or emergency department at Liaquat National hospital, will be included in the study after taking informed and written consent. The study will start after the approval of synopsis by CPSP and Ethical and Review board of Liaquat National Hospital.

Patients will be randomly allocated into two groups according to lottery method. The randomization process will be performed using random allocation and patients divided in ratio 1:1. Patients will be randomly assigned to one of the two study groups; group one (tamsulosin), and group two (solifenacin)

on the day of the surgery after placement of the stent. Patients in group 1 will receive tamsulosin capsule (Brand: Cap Tamsolin) 0.4 mg/day, while patients in group 2 will receive solifenacin tablet (Brand: Tab Solifen) 5 mg/day. The cost will be beard by the patient as these medications are routinely given to the patient post DJ stenting, irrespective of their participation in the study. The medication will be taken until removal of the stent. Patients will be reviewed 2 weeks after stenting in opd. The USSQ is the only validated scoring system for evaluation of ureteral stent-related symptoms [9] and therefore has to be used for comparing different treatments for alleviation of these symptoms. USSQ translated into Urdu will be used for patients who are unable to answer questionnaire in English [10].

DATA ANALYSIS PROCEDURE:

Patient's data will be compiled and analyzed through statistical package for Social Sciences (SPSS) Version 25. Normality of the data will be checked by Shapiro wilk's test. Mean±SD will be calculated for quantitative variable for groups i.e. age, height, weight, body mass index, length of stent placed and total USSQ score. If the data is non normal, median (iqr) will be reported instead of mean± SD. Frequency and percentage will be computed for qualitative variables for groups like gender, any addiction, diabetes, hypertension, smoker, occupation, surgical procedure and indications of stent placement. ANOVA will be applied to see the mean differences between groups. Chi square test or Fischer exact test will be used for finding association between categorical variables. Post stratification will be done on age, gender, height, weight, body mass index, any addiction, diabetes, hypertension, smoker, occupation, surgical procedure and indications of stent placement to see the effect of these modifiers on outcome. P-value ≤ 0.05 will be considered as significant.

ETHICAL CONSIDERATION:

Conducting a randomized control trial (RCT) comparing alpha-blocker and anti-cholinergic drugs involves several ethical considerations. It's crucial to prioritize the well-being and rights of participants while ensuring scientific rigor. Here are some ethical concerns associated with this a trial:

1. **Informed Consent:**

   Ensuring that participants fully understand the nature of the study, potential risks, benefits, and alternatives before providing informed consent. It will be clearly communicated that participation is voluntary, and individuals have the right to withdraw at any time without facing negative consequences.

2. **Participant Selection and Equity:**

   Ensuring that the selection criteria for participants are fair and do not disproportionately exclude certain demographic groups, potentially leading to biased results.

3. **Confidentiality and Privacy:**

   Safeguarding participant confidentiality and privacy by implementing robust data protection measures. Clearly communicating how participant data will be handled, stored, and shared to maintain trust and comply with relevant privacy regulations.

4. **Publication and Reporting:**

   Committing to transparent and timely reporting of study results, whether positive or negative, to contribute to scientific knowledge and prevent publication bias.

In case of any adverse event, the patient will contact us in LNH emergency. However, we have not come across any adverse/ critical adverse effect till date.

The researcher bears no financial responsibility.

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ANNEXURE-I PROFORMA

GROUP:_____

Serial No: _____ Case No: _____

Patient's Name: _____

Patient's contact #: _____

S/O, D/O, W/O:_____

Patient's Age: _____ years

Gender: ___Male ___Female

Height: _____

Weight: _____

BMI: _____

Any Addiction: Yes ___No _____

Diabetes: ___Yes ___No

Hypertension: ___Yes ___No

Smoker: ___Yes ___No

Occupation: _____

Surgical Procedure: _____

Indication of stent placement: _____

Date of stent placement: _____

Length of stent placed: _____ (cm)

Total USSQ score: _____

ANNEXURE-II USSQ(Stent in situ)

We are interested to know about various aspects of your health, following insertion of the stent and the effect the stent has had on your health.

Please complete the following questionnaire, which has different sections. Please answer all questions in each section.

(We would be grateful if you could complete and post the questionnaire within seven days)

Please complete:

Today's Date: ☐☐ / ☐☐ / ☐☐

Date of Birth: ☐☐ / ☐☐ / ☐☐

You will see that some questions ask if you have a symptom occasionally, sometimes or most of the time.

Occasionally	=	**less than one third of the time**
Sometimes	=	**between one and two thirds of the time**
Most of the time	=	**more than two thirds of the time**

URINARY SYMPTOMS

Please answer the questions thinking about the urinary symptoms you have experienced following insertion of the stent.

Please put a tick in one box for each question ☑

Please think about your experience since insertion of the stent.

U1. During the day, how often do you pass urine, on average?

- Less than hourly ☐ 5
- Hourly ☐ 4
- Every 2 hourly ☐ 3
- Every 3 hourly ☐ 2
- Every 4 hours or more ☐ 1

U2. During the night, how many times do you have to get up to pass urine, on average?

- None ☐ 1
- 1 ☐ 2
- 2 ☐ 3
- 3 ☐ 4
- 4 or more ☐ 5

U3. Do you have to rush to the toilet to urinate?

- Never ☐ 1
- Occasionally (less than one third of the time) ☐ 2
- Sometimes (between one and two thirds of the time) ☐ 3
- Most of the time (more than two thirds for the time) ☐ 4
- All of the time ☐ 5

U4. Does urine leak before you can get to the toilet?

- Never ☐ 1
- Occasionally ☐ 2
- Sometimes ☐ 3
- Most of the time ☐ 4
- All of the time ☐ 5

U5. Do you leak urine without feeling the need to go to the toilet?

- Never ☐ 1
- Occasionally ☐ 2
- Sometimes ☐ 3
- Most of the time ☐ 4
- All of the time ☐ 5

U6. how often do you feel that your bladder has not emptied properly after you have passed urine?

Never ☐ 1
Occasionally ☐ 2
(less than one third of the time)
Sometimes ☐ 3
(between one and two thirds of the time)
Most of the time ☐ 4
(more than two thirds for the time)
All of the time ☐ 5

U7. Do you have a burning feeling when you pass urine?

Never ☐ 1
Occasionally ☐ 2
Sometimes ☐ 3
Most of the time ☐ 4
All of the time ☐ 5

U8. How often do you see blood in your urine?

Never ☐ 1
Occasionally ☐ 2
Sometimes ☐ 3
Most of the time ☐ 4
All of the time ☐ 5

U9. How much blood do you see in your urine?

Do not see any blood ☐ 1
Urine is slightly blood stained ☐ 2
Urine is heavily blood stained ☐ 3
Urine is heavily blood stained and has clot(s) ☐ 4

U10. Overall, how much of a problem are your urinary symptoms to you?

Not at all ☐ 1
A little bit ☐ 2
Moderate ☐ 3
Quite a bit ☐ 4
Extreme ☐ 5

U11. If you were to spend the rest of your life with the urinary symptoms, if any, associated with the stent just the way they are, how would you feel about it?

Delighted ☐ 1
Pleased ☐ 2
Mostly satisfied ☐ 3
Mixed feelings (about equally satisfied and dissatisfied ☐ 4
Mostly dissatisfied ☐ 5
Unhappy ☐ 6
Terrible ☐ 7

Please go to next section --

BODY PAIN (for women):

This section asks about the **body pain or discomfort, which you associate with the stent.**

Please think about your experience **following insertion of the stent.**

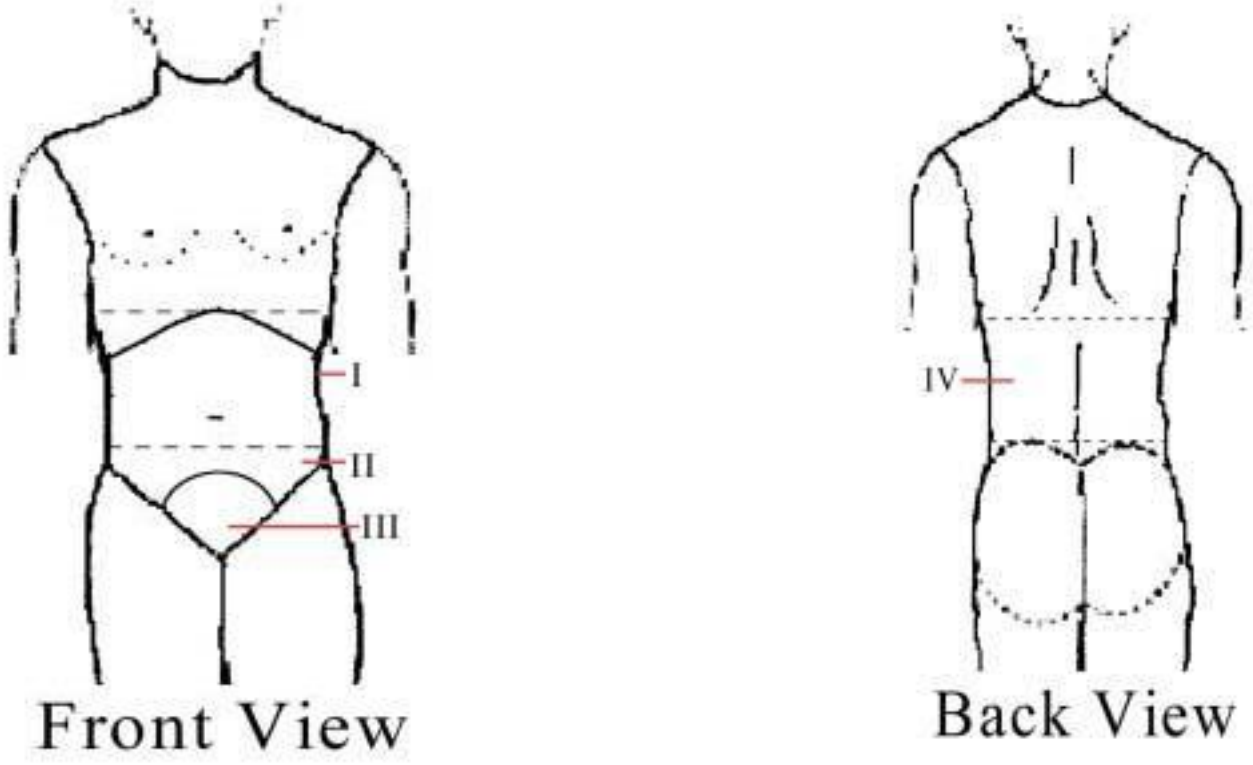
P1. Do you experience body pain or discomfort in association with the stent?

YES ☐ 1, **please go to question P2**

NO ☐ 2, **please go to next section on General Health** (Ignore questions P2 to P9)

P2. Think of the drawings below as the drawings of your body. Please **mark (X) or shade the site(s) where you experience pain or discomfort in association with the stent typically (e.g. during the day to day activities, whenever you pass urine)**

If you get pain at more than one site, please use a separate mark for each site.

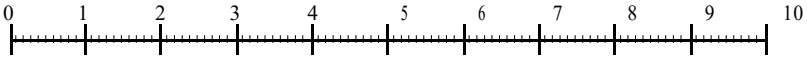


The numbers I - IV represent following areas for the right and left sides

I – Kidney front/side area **III** – Bladder area **II -** Groin area **IV**– Kidney back (loin) area

Please use O for any other marked area and write the name of the site

P3. Please place a mark (X) to a point on the line below that indicates your pain or discomfort in association with the stent. **Please put a separate mark for each site** if the pain or discomfort is different in severity and write the corresponding number of each site used in the drawing above**.**



No Pain or discomfort **Worst Possible Pain**

BODY PAIN (for men):

This section asks about the **body pain or discomfort, which you associate with the stent.**

Please think about your experience **following insertion of the stent.**

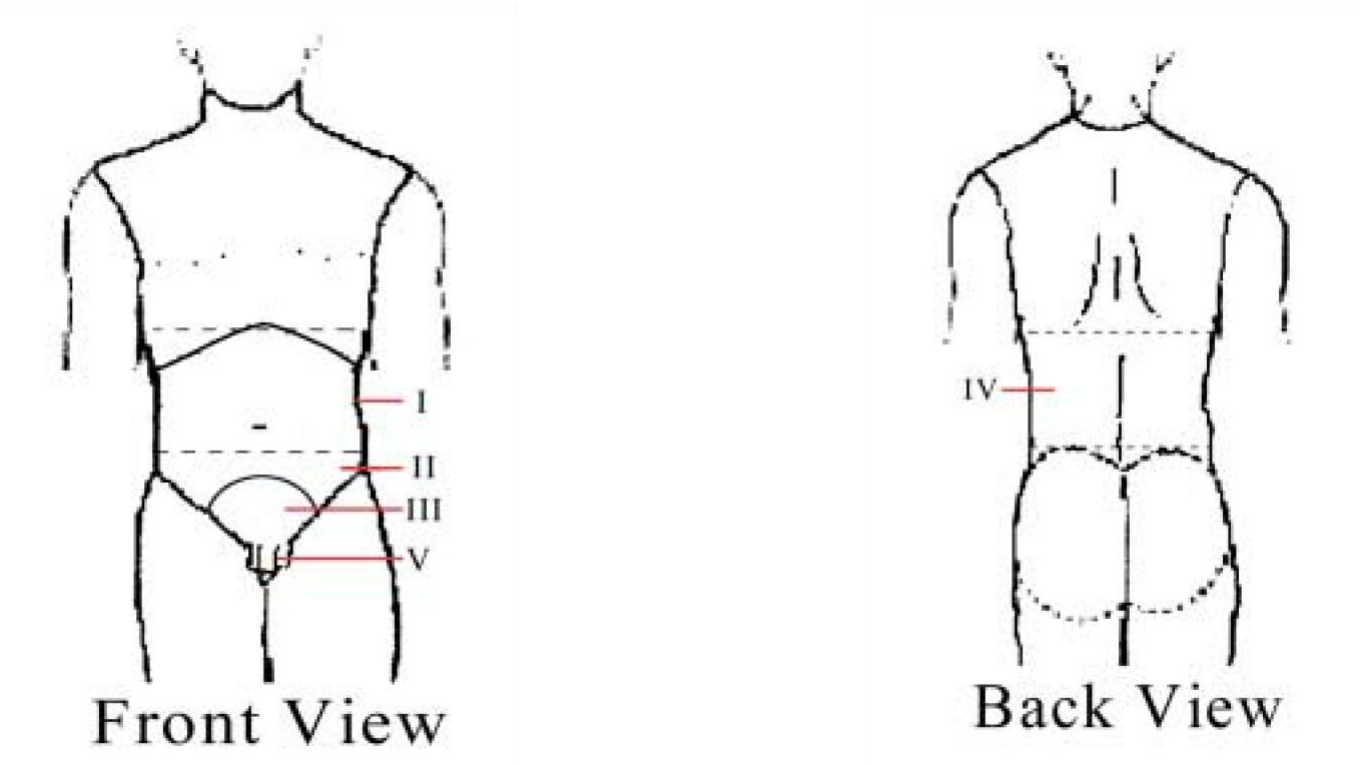
P1. Do you experience body pain or discomfort in association with the stent?

YES 1, **please go to question P2**

NO 2, **please go to next section on General Health** (Ignore questions P2 to P9)

P2. Thinking the drawings below as the drawings of your body, **mark (X) or shade the site(s) where you experience pain or discomfort in association with the stent typically (e.g. during the day to day activities, whenever you pass urine)**

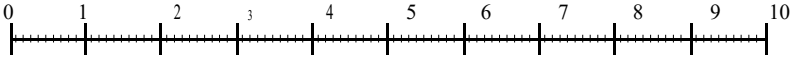
If you get pain at more than one site, please use a separate mark for each site.



The numbers I - V represent following areas for the right and left side.

I – Kidney front/side area
II - Groin area
III – Bladder area
IV– Kidney back (loin) area
V – Penis
Please use **O** for any other marked site and name that site.

P3. Please place a mark (X) to a point on the line below that indicates your pain or discomfort in association with the stent. **Please put a separate mark for each site** if the pain or discomfort is different in severity and write the corresponding number of each site used in the drawing above**.**



No Pain or discomfort **Worst Possible Pain**

P4. Which of the following statements best describe your experience regarding <u>physical activities</u> and the pain or discomfort in association with the stent?

I **do not experience any pain** or discomfort during physical activities ☐ 1

I experience pain or discomfort only when I perform **vigorous activities** ☐ 2
(e.g. strenuous sports, lifting heavy objects)

I experience pain when I perform **activities of moderate severity** but not with basic activities ☐ 3
(e.g. walking few hundred yards, driving a car)

I experience pain even when I perform **basic activities** of daily living ☐ 4
(e.g. walking indoors, dressing)

I experience pain while also **being at rest** ☐ 5

P5. Does the pain or discomfort, in association with the stent, interrupt your sleep?

Never ☐ 1 Most of the time ☐ 4

Occasionally ☐ 2 All of the time ☐ 5

Sometimes ☐ 3

P6. Do you experience pain or discomfort, in association with the stent, while passing urine?

Never ☐ 1 Most of the time ☐ 4

Occasionally ☐ 2 All of the time ☐ 5

Sometimes ☐ 3

P7. Do you experience pain or discomfort in the <u>kidney area</u>, while passing urine?

No ☐ 1

Yes ☐ 2

P8. How frequently have you required painkillers to control the pain or discomfort associated with the stent?

Never ☐ 1 Most of the time ☐ 4

Occasionally ☐ 2 All of the time ☐ 5

Sometimes ☐ 3

P9. Overall, how much does the pain or discomfort, in association with the stent, (as distinct from other symptoms) interfere with your life?

Never ☐ 1 Most of the time ☐ 4

Occasionally ☐ 2 All of the time ☐ 5

Sometimes ☐ 3

Please go to next section --

GENERAL HEALTH:

Following insertion of the stent:

G1. Have you had difficulty in performing light physical activities (e.g. walking short distances, driving a car)?

Usually with no difficulty ☐ 1
Usually with some difficulty ☐ 2
Usually with much difficulty ☐ 3
Usually did not do because of the stent ☐ 4
All of the time ☐ 0

G2. Have you had difficulty in performing heavy physical activities (e.g. strenuous sports, lifting heavy objects)?

Usually with no difficulty ☐ 1
Usually with some difficulty ☐ 2
Usually with much difficulty ☐ 3
Usually did not do because of the stent ☐ 4
All of the time ☐ 0

G3. Have you felt tired and worn out?

Never ☐ 1
Occasionally (less than one third of the time) ☐ 2
Sometimes (between one and two thirds of the time) ☐ 3
Most of the time (more than two thirds of the time) ☐ 4
All of the time ☐ 5

G4. Have you felt calm and peaceful?

All of the time ☐ 1
Most of the time (less than one third of the time) ☐ 2
Sometimes (between one and two thirds of the time) ☐ 3
Occasionally (more than two thirds of the time) ☐ 4
Never ☐ 5

G5. Have you enjoyed your social life (going out, meeting friends and so on)?

All of the time ☐ 1
Most of the time ☐ 2
Sometimes ☐ 3
Occasionally ☐ 4
Never ☐ 5

G6. Have you needed extra help from your family members or friends?

Never ☐ 1
Occasionally ☐ 2
Sometimes ☐ 3
Most of the time ☐ 4
All of the time ☐ 5

Please go to next section –

WORK PERFORMANCE:

W1. Regarding your employment status, are you

In full time employment ☐ 1 Student ☐ 4

In part time employment ☐ 2 Unemployed, looking for work ☐ 5

Retired on health ground ☐ 3 Retired for other reason (including age) ☐ 6

Not working for other reason (please specify) ☐ 7 _____

W2. Following insertion of the stent, how many days did the symptoms associated with the stent keep you in bed all or most of the day?

☐☐ Day(s)

W3. Following insertion of the stent, for how many half days or more did you cut down your routine activities because of the symptoms associated with the stent?

☐☐ Half Day(s)

Please answer the questions below (W4 –W7) only if you are in active paid work.

(Otherwise ignore questions W4 – W7).

W4. a) Job title or description of your role: _____

b) Are you an: Employee ☐ 1 Employer ☐ 2 Self employed ☐ 3

Please answer following questions if you have worked after insertion of the stent,

W5. Have you worked for short periods of time or taken frequent rests because of the symptoms associated with the stent?

Never ☐ 1 Most of the time ☐ 4

Occasionally ☐ 2 All of the time ☐ 5

Sometimes ☐ 3

W6. Have you worked at your usual job, but with some changes because of the symptoms associated with the stent?

Never ☐ 1 Most of the time ☐ 4

Occasionally ☐ 2 All of the time ☐ 5

Sometimes ☐ 3

W7. Have you worked your regular number of hours?

Never ☐ 1 Most of the time ☐ 4

Occasionally ☐ 2 All of the time ☐ 5

Sometimes ☐ 3

Please go to next section –8

SEXUAL MATTERS:

Please tick one box for each question by thinking about **your experience following insertion of the stent**.

S1. Currently, do you have an active sex life?

No ☐ 1, Please answer question S2 and go to next section (Ignore questions S3 and S4).

Yes ☐ 2, Please go to question S3 (Ignore question S2).

S2. (i) If NO sex life, how long ago did this stop?

After insertion of the stent ☐ 1

Before insertion of the stent ☐ 0

(ii)AND, why did this stop?

Because of the problems associated with the stent ☐ 10

Did not attempt any sexual activity ☐ 0

Some other reason – not to do with the symptoms of the stent ☐ 0

(Ignore questions S3 – S4)

Please answer questions S3 and S4, only if you have answered 'yes' to question S1.

Please think about your experience following insertion of the stent.

S3. Do you have pain when you have sexual intercourse?

Not at all ☐ 1

Mild ☐ 2

Moderate ☐ 3

Severe ☐ 4

Extreme ☐ 5

S4. How satisfied are you with your sex life?

Very satisfied ☐ 1

Satisfied ☐ 2

Not sure ☐ 3

Dissatisfied ☐ 4

Very dissatisfied ☐ 5

Please go to next section ---

ADDITIONAL PROBLEMS:

The following questions ask about your experience following insertion of the stent. Please indicate your experience by ticking the appropriate box.

A1. How many times have you felt you may be suffering from a urinary tract infection (e.g. running temperature, feeling unwell and pain while passing urine)?

Never ☐ 1
Occasionally ☐ 2
Sometimes ☐ 3
Most of the time ☐ 4
All of the time ☐ 5

A2. Have you needed to take antibiotics as a result of insertion of the stent? (Please ignore the course of antibiotics, which may have been given at the time of insertion of the stent.)

Not at all ☐ 1
One Course ☐ 2
Two Courses ☐ 3
Three or more Courses ☐ 4

A3. Have you needed to seek help of a health professional (such as GP, nurse) due to any problem associated with the stent?

Never ☐ 1
Once ☐ 2
Twice ☐ 3
Three or more times ☐ 4

A4. Have you needed to visit the hospital due to any problem associated with the stent?

Never ☐ 1
Once ☐ 2
Twice ☐ 3
Three or more times ☐ 4

GQ In the future, if you were advised to have another stent inserted, how would you feel about it?

Delighted ☐ 1
Pleased ☐ 2
Mostly satisfied ☐ 3
Mixed feelings (about equally satisfied and dissatisfied) ☐ 4
Mostly dissatisfied ☐ 5
Unhappy ☐ 6
Terrible ☐ 7

AQ. If there are any comments you would like to make about the questionnaire or any of your symptoms, please use the space below.

THANK YOU VERY MUCH FOR YOUR HELP

All information will remain confidential

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