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Male Infertility Treatment Unveiled: Exploring New Horizons with Q-Well 10 - Results from a Pioneering Medical Study

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Abstract

Introduction: The principal androgen controlling spermatogenesis in the testis is T. By diffusing into the seminiferous tubules, which are home to the Sertoli cells, it functions as a paracrine factor. It is secreted by Leydig cells as a reaction to the luteinizing hormone (LH) signal. Aminopeptidase N (APN) is an enzyme of semen that is frequently present in multiple cell types and is linked to a number of illness states, including cancer, hypertension, neoplasm, inflammation, and obesity. Human seminal plasma has a 20-fold higher APN activity than brain cells.

Aims and objective: To determine the efficacy of Q-Well 10, as compared to control patients, in the improvement of reproductive biochemical markers.

Methods: This study has been conducted on 80 infertile males in Salah Al-Din Governorate. They were divided into two groups; namely, the "Drug" group, which received the drug named "Q-Well 10", and a second group, considered as the "Control" group. Recruitment of these infertile males was done by community outreach programs and advertisement. Before the study treatment was started, the baseline data were collected from all the participants. The data collection included measurements of blood pressure, body weight, height, and blood samples for laboratory analysis. Semen samples were obtained by masturbation after 2 to 7 days of abstinence, and fasting venous blood was extracted to get serum samples. After the treatment period (4-6 weeks), the same measurements and laboratory tests were repeated to assess the health outcomes of the participants.

Results: The study found that improvement in several parameters occurred after 4 to 6 weeks of treatment with the drug "Q-Well 10". There was a significant difference in various parameters between the "Q-Well 10" group and the control group after receiving the drug. The parameters like Amylin, AAP, GGT, Inhibin, LH, FSH, Testosterone, had significantly improved compared to the control group (P<0.005).

Conclusion: Conclusion: The study concluded that there is significant improvement in the abnormality of males' sterility with the drug "Q-Well 10" as compared to receiving no treatment. "Q-Well 10" has shown to be beneficial in the sterility of males.

Keywords: sterility, amylin, alanine aminopeptidase, infertility, Q-Well, male fertility.

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Introduction

Nearly 41–50% of couples with infertility are caused by male factors, and studies show that general semen parameters have significantly decreased over the past ten years. Analysis of semen is the primary method used to study male factor sterility, but its predictive power is still somewhat restricted. 15% of male infertile males have been found to have low blood serum testosterone (T) [1,2]. The principal androgen controlling spermatogenesis in the testis is T. By diffusing into the seminiferous tubules, which are home to the Sertoli cells, it functions as a paracrine factor. It is secreted by Leydig cells as a reaction to the luteinizing hormone (LH) signal. The androgen receptor (AR), which is found in both the nucleus and cytoplasm, mediates the effects of T signaling on Sertoli cells [3,4].

Mammalian semen contains aminopeptidase N (APN), an ectopeptidase that exists naturally. Prior research has shown that APN alters sperm motility, which has a negative impact on male fertility. This enzyme makes up between 0.7 and 1.1% of plasma proteins of semen, which are capable of being fused from prostasomes to sperm [5,6]. In the human body, aminopeptidase N (APN) is an enzyme of semen that is frequently present in multiple cell types and is linked to a number of illness states, including cancer, hypertension, neoplasm, inflammation, and obesity. Human seminal plasma has a 20-fold higher APN activity than brain cells. According to Arienti et al., a pH-dependent fusion mechanism is used by APNs to go from the seminal plasma vesicle to the sperm membrane [7,8].

Semen from subfertile guys exhibits comparatively high APN activation than that of their fertile counterparts, according to a review of the literature. Furthermore, both soluble and particulate sperm fractions show a positive correlation between the percentage of dead spermatozoa and APN activity. Similarly to this, Subiran et al. found that total suppression of APN improved sperm motility in mouse spermatozoa [9]. A substantial positive connection between APN activity and the proportion of spermatozoa with aberrant apical ridges and total sperm abnormalities has also been noted. The precise function of this enzyme in controlling sperm processes associated with male fertility, including motility, the acrosome reaction, capacitation, and PKA activity protein tyrosine phosphorylation, is not known despite the early insights these discoveries offered [10-12].

In Aside from its well-known effects on organs such as the eye, heart, and kidney, diabetes is a complicated metabolic and systemic illness that also affects male reproduction. Type 1 diabetes and type 2 diabetes are the two main types. An increased incidence of diabetes in males of reproductive age is mirrored by the pandemic rise in diabetes, amplifying the hazards to reproductive health and adding to the already alarming global reduction in male sterility [13]. In fact, it has been noted that guys with diabetes are more likely to have infertility and subfertility. Also, it was revealed that a sizable portion of patients who seek

fertility treatments had diabetes. Despite the fact that rates of fertilization and embryo development were unaltered, pregnancy rates are much lower in couples with diabetic male partners [14,15].

Diabetes has been linked to decreased sperm concentration, motility, and normal morphology as well as enhanced nuclear and mitochondrial DNA damage and altered sperm mitochondrial function, all of which are likely caused by supra-physiological glucose levels and associated oxidative stress [16].

Seminiferous tubules are reduced in size, multinucleated germ cells are present, degeneration and apoptosis are high, germ cells are depleted, the apical membrane of Sertoli cells is altered, the junction between Sertoli and germ cells is anomalous, Sertoli and Leydig cells vacuolize, lipid droplets aggregation occurs in Leydig cells, and their number is decreasing, which may decrease fertility and spermatogenesis [17].

Materials and Methods

Research Design:

This study was conducted on 80 infertile males in Salah Al-Din Governorate from May to September 2021. Participants were divided into two groups; namely, the "Drug B" group which received the drug named "Q-Well 10," and another group that was considered as the "Control" group. Recruitment of these infertile males was done by community outreach programs and advertisements. They were screened for eligibility based on inclusion criteria, such as age between 20-49 years and absence of any chronic diseases or medication use.

Participants were assigned randomly to either the "Drug B" group or the "Control" group. The randomization process ensured equal representation of age groups in each group. The recommended dosage and duration for "Q-Well 10" was maintained. The control group received no treatment.

Before the study treatment was started, baseline data was collected from all the participants. This included measurements of blood pressure, body weight, height, and blood samples for laboratory analysis. Semen samples were obtained by masturbation after 2 to 7 days of abstinence, and fasting venous blood was extracted to get serum samples. Following regular semen analysis, semen specimens were placed at 37°C for liquefaction. The remaining semen samples were then centrifuged at 12,000 g for 5 minutes. To identify biochemical indicators, a higher layer of seminal plasma was taken. Blood samples were centrifuged at 3000 g for 5 minutes to isolate serum for the same analysis as for seminal plasma. All biochemical markers underwent calibration and quality control product determination, using specific analyzers such as a PSD-16a Electrolyte Analyzer and an Olympus AU400 Automated Biochemical Analyzer.

After the treatment period (4-6 weeks), the same measurements and laboratory tests were repeated to assess the health outcomes of the participants,

providing an insightful evaluation of the efficacy of “Q-Well 10” in the treatment of male infertility. The research methodology implemented is indicative of a rigorous and carefully planned approach to evaluate this specific treatment.

Inclusion and Exclusion Criteria

The study considered males with absence of clinical fertility for over 2 years. Males between 20 to 49 years old were included in the study. The male person who followed our study protocol were only included. The participant who did not gave consent or dropped out in the middle of the study process, was excluded. The participant who had received prior treatment of infertility was also excluded. The participant with chronic disease like hypertension or diabetes and who are on longer treatment of other drugs were also excluded. To eliminate any potential impact on sampling accuracy and to assure the detection of all biochemical markers, all nonliquefaction and volume samples of semen with a volume of less than 1.5 mL were excluded.

Statistical Analysis

The data was arranged in Excel and analyzed using the SPSS 25.0 software (SPSS Inc., Chicago, USA). The continuous data was expressed as mean \pm standard deviation while discrete data was expressed as frequency and percentages.

By using SPSS, the study conducted paired t-test to evaluate the values of biochemical parameters in seminal plasma and serum, $P < 0.05$ was taken into account as a significant difference. Using Pearson analysis, the correlation between biological parameters in seminal serum and plasma was examined, and it was determined to be a significant association.

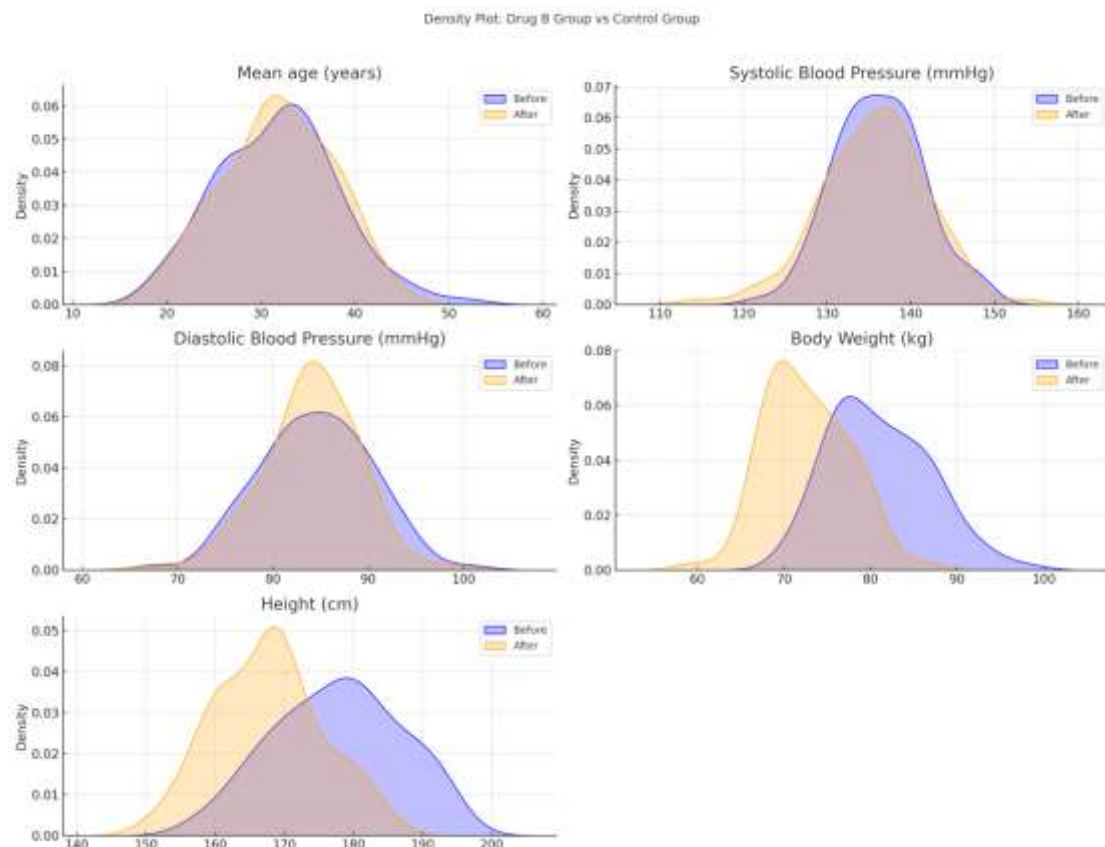
Ethical Approval

The study gave a thorough explanation to each participant before collection of samples. The written consent have been obtained from each . The Ethical Committee approved the study's methodology.

Results

The study revealed that the mean age of participants in the 'Drug B' group was 32.14 ± 6.41 years. In addition to age, essential physical parameters such as body weight, height, and both systolic and diastolic blood pressure were systematically recorded for this specific group. This information aids in providing a well-defined characterization of the participants in the 'Drug B' group, allowing for detailed analysis and understanding of the study's outcomes. Table 1: Baseline features and vitals of the participants in all the groups that are considered for this study

Parameters	Drug B group	Control
Number	30	20
Mean age (years)	32.14±6.41	31.95±5.4
Blood Pressure		
Systolic (mmHg)	136.48±5.25	135.47±6.25
Diastolic (mmHg)	84.52±6.12	83.65±5.42
Body Weight (kg)	81.35±5.55	72.45±4.58
Height (cm)	178.35±9.45	168.55±8.54



The study discovered a notable improvement in various parameters after 4 to 6 weeks of treatment with the specified drug. B significant difference was observed in several parameters between the group receiving the drug and the control group. Parameters such as Amylin, AAP, GGT, Inhibin, LH, FSH, and

Testosterone exhibited significant improvement in comparison to the control group ($P < 0.005$). These findings underscore the potential effectiveness of the specific drug under investigation in enhancing these key biological factors.

Table 2: This research examines the biochemical outcomes of various enzymes and hormones in three studied groups, before and after drug treatment.

Parameters	Before receiving the drug		After receiving the drug		P-value
	Drug B group	Control	Drug B group	Control	
Amylin (ng/ml)	5.6±0.5	5.7±0.1	26.6±0.5	9.56±0.5	0.0413
AAP	13.21±1.24	12.36±1.24	32.44±3.1	19.65±4	0.0421
GGT	21.44±3.57	20.35±1.44	33.65±3.5	24.56±4	0.049
Adiponectin	16.85±4.25	16.45±3.25	20.58±2.9	15.95±1	0.698

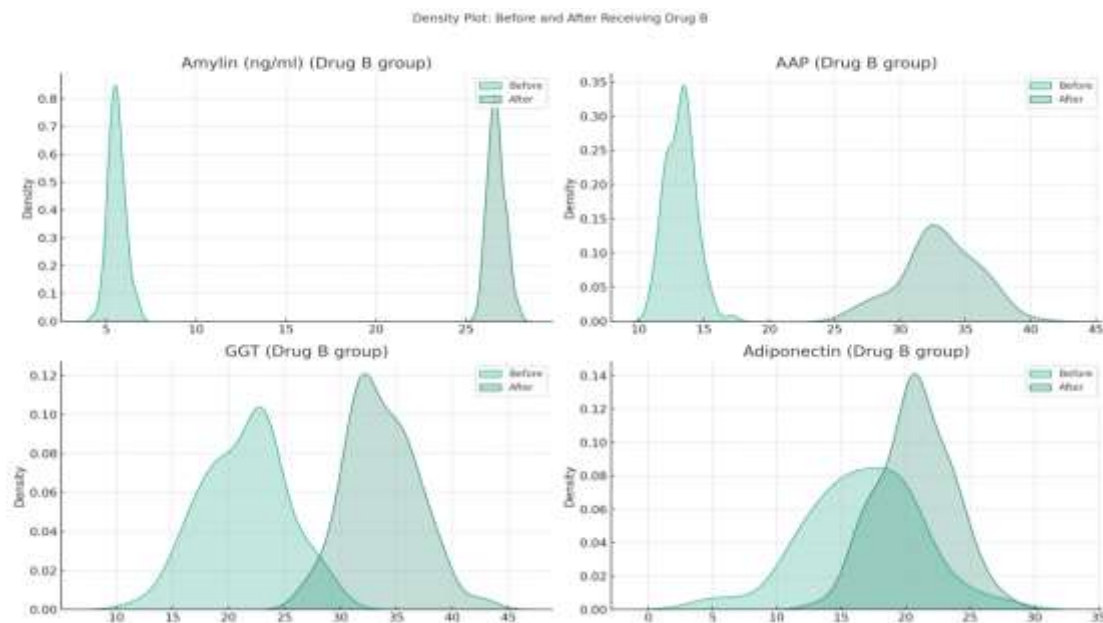
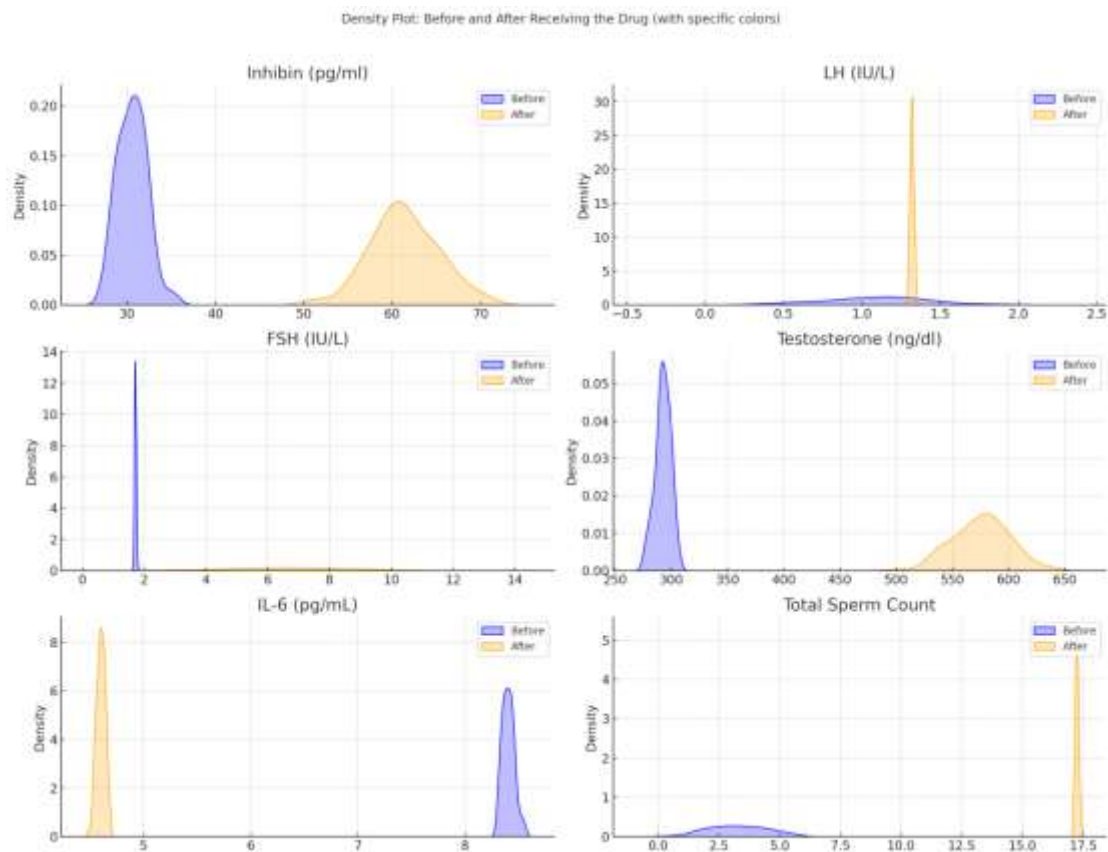


Table 3: The biochemical results of several enzymes and hormones before and after the drug treatment between 3 studied groups of this research

	BEFORE RECEIVING THE DRUG		AFTER RECEIVING THE DRUG		
Inhibin (pg/ml)	30.55±1.6	31.41±1.25	61.58±3.6	48.58±3.2	0.045
LH (IU/L)	1.12±0.	1.1±0.6	1.32±0.01	1.16±0.0	0.048

	36	2		7	
FSH (IU/L)	1.71±0.03	1.71±0.02	7.10±1.9	3.2±0.9	0.045
Testosterone (ng/dl)	291.52±7.36	292.36±5.85	580.54±25.85	312.52±12.25	0.035
IL-6 (pg/mL)	8.41±0.06	8.42±0.06	4.6±0.04	5.3±0.03	0.0512
Total Sperm Count	3.14±1.32	3.18±1.18	17.25±0.07	12.05±1.1	0.035



Discussion

In a previous study, the free amino acid (AA) levels in the blood of infertile males were investigated. Tryptophan and alanine levels were significantly less in men with low motility rates, whereas aspartate and glutamate levels were significantly lower in men with high aberrant morphology rates. According to the study's findings, AAs, particularly oligozoospermia, are likely involved in the pathophysiology of male infertility [18].

Men who are unable to naturally fertilize a viable female are said to be male infertile. Male infertility cannot be diagnosed just based on a basic semen study. It is essential to have specialized assays for determining the integrity of the chromatin. To assess sperm chromatin quality in fertile males and the infertile subgroup, a study was carried out. Conventional sperm nuclear maturities tests, such as aniline blue (AB) and toluidine blue (TB) staining, and

semen analysis were performed. The use of AB and TB to dye sperm chromatin revealed a negative correlation between sperm chromatin condensation and sperm count, normal morphology, and progressive motility. It appears that evaluating male reproductive potential may benefit from the AB and TB tests [19].

The fluid found in the human seminal vesicles is intricate. The number of proteins expressed in seminal plasma is unknown, however similar to blood, it is likely that up to 10,000 proteins are expressed there. A wealth of possible biomarkers for male infertility and reproductive disorders can be found in human seminal fluid. The human seminal plasma proteome database was updated as part of this work. Our research revealed that the human seminal plasma studies conducted to date appear to have focused on a group of proteins that have been frequently discovered in numerous studies but only make up a small portion of the total proteome of the human seminal plasma [20].

By screening, early diagnosis, and more precise prognosis, molecular biomarkers have the potential to advance the noninvasive diagnosis of illnesses of the male reproductive system and to make it easier to identify and treat these conditions. Seminal plasma has considerable potential as a clinical sample for noninvasive diagnostics and as a proximal fluid for protein biomarker identification. There are thousands of proteins in the seminal plasma proteome, many of which are tissue-specific and may correctly predict a diseased state in the tissue of origin. Possible protein biomarkers for problems with the male reproductive system are more prevalent in seminal plasma than in blood serum or urine, making it simpler to detect and measure them in semen using mass spectrometry and other methods. The seminal plasma proteome's composition and the tissue specificity of seminal plasma proteins have been elaborated thanks to these techniques. By integrating 'omics' methodologies, methods have been developed to find protein biomarkers in seminal plasma. Seminal plasma clearly has the potential to enhance other diagnostic tools now used in urology clinics, especially as biomarkers of male infertility and prostate cancer are increasingly becoming more widely recognized [21].

Sperm chromatin structure can be assessed using the toluidine blue (TB) test. Using clearly defined groups of fertile and infertile men, a study was done to determine the clinical utility of the TB test in determining male reproductive potential. According to the study's findings, the TB test can be recommended for clinical usage as a test to supplement traditional semen analysis in order to detect male infertility [22-25].

Men who were normozoospermic, oligozoospermic, obstructive, and non-obstructive azoospermic had their seminal plasma aminopeptidase levels examined. Non-obstructive azoospermic patients showed much higher activity than the other three categories. Comparing several aminoacyl beta-naphthylamide hydrochlorides that were utilized to determine substrate specificity, it was discovered that L-Alanine had the highest rate of hydrolysis.

[26-29]. EDTA and 1,10-phenanthroline both produced 50% inhibitions of the enzyme activity at doses of 5.77×10^{-3} M and 3.13×10^{-6} M, respectively. For all subcategories of seminal plasma, a single band for aminopeptidase was identified in the activity-gel electrophoresis, and the enzymes displayed metalloprotein properties [30-32].

Biomarkers for a variety of male reproductive system problems, such as male infertility, may be found in seminal plasma. With the advent of high-throughput MS-based techniques, understanding of the protein and peptide constituents of seminal fluid is increasing. [33-39]. The discovery and characterisation of proteins with variable expression in seminal plasma of men with normal and defective spermatogenesis is particularly interesting in the realm of male infertility biomarkers. The data collected up to this point is still highly varied, and there is only a tiny amount of overlap between different investigations. To determine a possible connection among seminal plasma proteins and male infertility, a thorough comparative investigation of the seminal plasma proteome is still required [40-49].

Conclusion

The study concluded that there is significant improvement in the abnormality of males' sterility with the drugs as mentioned with respect to receiving no treatment. The drugs "Motility Max" and "Q-Well 10" have shown to be beneficial in sterility of male. In conclusion, only the level of UA did not significantly differ between seminal plasma and serum among the 26 biochemical markers we investigated. Although seminal plasma contained a variety of proteins, globulin predominated over other proteins, unlike serum. In addition, seminal plasma included a wealth of enzymes, and all enzyme activity, with the exception of ADA, were much higher in seminal plasma than in serum. There are several limitations to this study. The study considered males from one region which definitely will reduce the credibility of the data and increase biases. Although there are no selection bias due to randomization, but due to limited sample, the data is not varied. There is a need to conduct more studies with varied data to bring out more credible conclusion. However, the study has brought forward clinical important findings which would help in the management of male infertility.

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