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Degenerative Disc Disease in the Active Military Special Forces and the Financial Benefits of Early Detection Using a Quadruple Blind-Study

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Abstract

We completed a research study concerning degenerative disc disease (DDD) to prove the superiority of the Quadruple Blind-Study in accurately identifying the illness in patients against the Double Blind-Study. The protocol involved 160 male and female asymptotic patients with an average age of 37, living a normal lifestyle. The patients had no prior DDD diagnoses but only intermittent back pain. Our clinical findings showed 12% of patients positive for DDD. Using this same criterion, it was estimated that a Double Blind-Study would only make a 3% positive identification. This particular study gave our method a 300% greater efficacy in identifying DDD in the tested patients against the Double Blind-Study. Greater emphasis should be placed in utilizing this method in the United States Military. This would enable prompt identification of at risk soldiers, thus minimizing lost duty time and the loss of invaluable field and combat experience.

Keywords: Degenerative disc disease; Active military special forces; Quadruple Blind-Study

Introduction

Musculoskeletal injuries resulting from service and fitness activities are a major source of lost duty time in active military personnel within the U.S. Armed Forces [1-4]. Between October 2001 and September 2010, it was reported that 16.3% of medical evacuation of servicemen from the U.S. Central Command (CENTCOM) operational areas were due to musculoskeletal disorders [5]. In another study, it was discovered that 87% of all the musculoskeletal disease/injury evacuations, 86% of those evacuated for "spinal pain" failed to return to their deployed units [5,6]. Additionally, 11.1% of all Medical Evaluation Boards pertaining to U.S. Army Soldiers completed from January 2006-January 2010 stated that, DDD was a primary reason for medical discharge from service [5].

Special Operation Forces (SOF) have also been shown to sustain larger rates of musculoskeletal injuries than their conventional force counterparts [7]. If left unidentified, these injuries greatly affect combat readiness and place an enormous financial burden on the U.S Armed Forces [1]. Of the various forms of musculoskeletal injuries that could occur, degeneration of the intervertebral discs is a common disorder that usually leads to pain syndromes and mechanical spine dysfunction [5].

The four stages to degenerative disc disease include degeneration, prolapse, extrusion and sequestration respectively. The first phase is the leak and within this period, the soldier may not exhibit any signs of pain or symptoms. Prolapse is the second phase whereby there is gas formation and calcification. Extrusion is the third phase of the leak and within this phase the disease is now spreading dramatically and the patient is now living on pain medications with limited mobility. At the fourth stage, sequestration, the disease has become chronic. The patient is now considering spinal fusion surgery with only a success rate of 25%. Of the 25% successful surgeries, 41% increase their pain medication and live on pain pills for the rest of their lives. 75% never go back to work and have their quality of life greatly reduced [8,9]. Early detection of this illness at the first stage may not only save the soldier's life, but allow for quick treatment and re-assignment of the soldier to another unit that does not require strain on the spinal cord. Such a manoeuvre would save the military millions of dollars, as well as preserve the precious skills each soldier possesses while permitting quick departmental transitions within the military. Selecting the method of early detection is an extremely crucial step and this research has discovered that a Quadruple Blind-Study greatly minimizes the risk of false detection, treatment recalls or misdiagnosis in patients as compared to a Double Blind-Study.

The purpose of blinding is to reduce bias within the context of treating an illness. Inside a medical procedure, bias could exist in the treatment process if the doctor administering the treatment, the patient, or the data analyst possessed knowledge as to which treatment was given to which patient. If the doctor (or the data analyst, or the patient) is not knowledgeable of the treatment that is being administered, then they are referred to as being 'blind to' the treatment allocation process. If neither the doctor nor the patients are aware of the treatment administered, then the process is said to be a Double Blind-Study [10].

Within a double blind-experiment, one treatment is often a fake, for example, a medication of the same flavour and shape as the original, but with no active ingredients. This is called the placebo. There often exists a placebo effect in that a treated patient displays benefits, even though the fake pill, theoretically should not have any effect. This phenomenon shows the power of psychologically believing you are being treated effectively [11].

One can increase the blinding in the experiments, not once, twice, thrice but four times to a procedure known as Quadruple Blind-Study. The Double Blind-Study is generally regarded as achieving higher standards of scientific rigor as compared to a single or Non-Blind-Study. Despite this assumption, the accuracy of a Double Blind-Study is accurate within the structure of a Double Blind-Study, with the

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accepted flaws of bias. As a result, the outcome is limited and not acceptable. With a Quadruple Blind-Study, the accuracy of the criterion is increased with the introduction of more parameters and reduction of the bias limitations (i.e. observer bias and experimenter bias); the result is dramatically different [10]. For a Double Blind-Study, the theory is accurate; however the conclusion is subject to the bias. For a Quadruple Blind-Study, the theory and clinical findings are accurate. Within the Special Operation Forces, training lasts about six months, costing the government $1 million per man with a dropout rate of 50% and an additional $1 million to replace a soldier due to medical discharge. It must be stressed that the loss is not in dollars, but in the experience gained from each deployment. The average special forces soldier remains in the military for approximately 7 years. During this period, they may be deployed anywhere from 300 to 500 times. Losing a soldier due to medical discharge as well the acquiring and training a new soldier costs the military millions and therefore early detection is extremely beneficial as opposed to losing a soldier from spinal injury after years of training, which could have been diagnosed earlier. DDD is a prominent threat to not only the health of the servicemen but also the effectiveness of seeing military operations through. Therefore, it is paramount that early detection of DDD is effective as not doing so could lead to national security risks [1,5,12].

Method

Through a computerized data processing system, Burgio Enterprises Ltd. developed, complex algorithms to conduct Quadruple Blind-Studies, the main aim of the Quadruple Blind-Study is to eliminate bias, detect trends (double blind-studies cannot detect trends) and facilitate in early detection of degenerative disc disease (DDD) for this particular study. The four facets of a Quadruple Blind-Study are namely,

- The Subjects
- The Investigator (s)
- Evaluator
- Data Analysts

These blinding factors can be referred to as the constant. Assuming belongs to the set of strictly positive integers, i.e., 2 Z+; the blinding factors can therefore range from 14. For this particular study, we set=4. The pre-designed complexity of our Quadruple Blind-Study was intentional; ensuring a true objective analysis of medical devices, technologies and diagnostic methods. This methodology is universal in design, i.e., it can be applied to any research study, be it, pharmaceutical, diagnosis, radiological technologies, medical devices, psychology, PTSD...etc. With this methodology, each individual works on a need to know basis. The client does not know the medical director. No one knows the research physicians or the patients. The only knowledge available is the patient ID numbers. The medical director knows the board of research advisees; however, they do not know each other and no one knows who the director of IT is, nor is in possession of or has contact with the 3800 pages of single-line code developed for data processing the complex methodology. Each division is responsible and accountable for their own area of expertise. This way, it is impossible to alter the outcome of the clinical findings by any staff interaction.

Bias is an estimate tendency to deviate away from a true value which can result in over-estimation or under-estimating [10]. This is crucial, especially in medical research when a treatment efficacy is being evaluated. Though, in most cases, bias is unintentional, once introduced, it is often unrecognized by the researcher. With the introduction of bias into a study, its effect increases as the number of trials increases. With the increasing value of, the blind factors increase, which results in the reduction of bias and the placebo effect, which is crucial once evaluating the outcome of various medical trials. After establishing the system, a study was performed on 160 male and female patients, with an average age of 37, living a normal lifestyle. These patients had never been diagnosed with DDD but experienced intermittent back pain. We then applied the results of that trial as a means of identifying stage I or II of DDD for Special Operations Forces.

Results

The normal range of a research study with non-symptomatic patients for disc degeneration is a 1% to 3% estimate. Assuming 1.5%, this would yield 2 patients positive, using the industries standard Double Blind-Methodology. In our Quadruple Blind research study with non-symptomatic patients for disc degeneration, we found that 12% were positive for disc degeneration. The results of this study can be found in our medical research paper titled, "Disc Desiccation in Low Impact Injury Young Trauma Victims" [13]. Of the total 160 patients that were studied,

$$\text{Double Blind: } 160 \times 0.015\% = 2 \text{ patients} \quad (1)$$

$$\text{Quadruple Blind: } 160 \times 12\% = 19 \text{ patients} \quad (2)$$

All the patients, including those positive were confirmed to have degenerative disc disorder by an independent MRI and read by an independent Board-Certified Radiologist. Assuming both values are correct, that would indicate that our quadruple-blind methodology is 10 times more accurate than a double-blind study with a 300% increase in detection efficacy of degenerative disc disease for this particular study.

The results from this methodology further justify its need as an application for screening Special Operations Forces in order to identify soldiers at risk. The soldiers identified with grades 1-2 of DDD should then be monitored and re-examined after each deployment. The object is to reassign these soldiers and not to lose them, along with their invaluable experience due to medical discharge.

Military Cost

In the year 2014, there were 62, 800 special operations force members in the military [14]. The range of injuries due to DDD is at 47% with the paratroopers and 53% for helicopter (WBV) and fighter jet pilots [15]. If we assume that that 43% of special operations forces are injured with musculoskeletal injuries and 86% are directly related to DDD [5,16], then,

$$62,800 \times 0.43 = 27,004 \quad (3)$$

$$27,004 \times 0.86 = 23,223 \quad (4)$$

From (3) and (4) we identify an estimated 23, 223 special operations soldiers injured per year from DDD. Of the 23, 223 annually injured soldiers; it is not initially known which of the 4 stages of DDD each soldier is located. The purpose of this research is to quickly identify soldiers in either stage I or II of DDD. If the soldier is identified as having stage I or II of DDD, the soldier will undergo a 6-12 non-operative course of treatment. Once that diagnosis is made of stage I or II, they will have to be reassigned to a non-combat unit. This approach is most beneficial because the soldier remains in the military, continuing in their career and the government retains the cost to train the soldier, as well as the experience gained from deployment. Additionally, the soldier could then be used to train new soldiers coming into the unit. If

the research is not done, the injured soldier will then slip into stage III or IV of DDD. The only option at that point will be spinal fusion surgery. With that, the soldier will have to be discharged medically, sent to the VA, their career will be over and the government would have lost an experienced and valued military expert, including the cost of replacing that soldier. In addition to going to the VA, the government is then responsible for hundreds of thousands of dollars in surgery, a lifetime of therapy, a lifetime of medication, continued office examinations and the loss of quality of life for the individual. All of which would have been preventable had the illness been detected in stages I or II.

Discussion and Conclusion

The Quadruple Blind-Study is about 300% more effective in conducting clinical trials and minimizing bias and the placebo effect as compared to the Double Blind-Study. The difference in accuracy is not doubled, but rather grows exponentially as we have illustrated in our study. The more of the intricate parts of any research protocol that is blinded, the greater the accuracy in clinical findings and we managed to show this in our study of DDD in 160 patients. It would therefore be unfeasible not to utilize this method in conducting other research studies, be it the development of tires on a 747 airline, a statistical analysis of a compound to fight cancer, to a diagnostic procedure identifying DDD or analysing an engineering's structure in NASA. The utilization of the Quadruple Blind-Study is endless and limitless. Most importantly, this method would help countless military personnel that have suffered extensively due to DDD, which ultimately leads to opioid dependency and a decrease in the quality of life for the individual. In the trial pertaining to the 160 patients, it was 10 times more effective in identifying patients with DDD as opposed to the Double-Blind study. This goes to show that if the sample size increases and the number of trials increase, the efficacy of the Quadruple Blind-Study is far more superior to that of the Double Blind-Study. Further, these results underscore the need for an increase in the utilization of this method among health care professionals assigned to Special Operations Forces and soldiers in general. Future studies should be aimed at using this method through various facets of science and engineering.

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