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# Ketofol vs Dexamedetomidine Effect on Conscious Sedation for Patients with Chronic Nonsurgical Low Back Pain

*Thesis*

***Submitted for Partial Fulfillment of M.D Degree in Anesthesiology***

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# List of Abbreviations

| Abb. | Full term |
|---|---|
| **ACEP** | American College of Emergency Physicians |
| **ADH** | Anti diuretic hormone |
| **CBC** | Complete blood count |
| **CNS** | Central nervous system |
| **COPD** | Chronic obstructive pulmonary disease |
| **DBP** | Diastolic blood pressure |
| **ECG** | Electrocardiogram |
| **ED** | Emergency Department |
| **ERCP** | Endoscopic Retrograde Cholangiopancreatography |
| **GABA** | Gamma-aminobutyric acid |
| **HR** | Heart rate |
| **IM** | Intramuscularly |
| **IV** | Intravenous |
| **JCAHO** | Joint Commission on Accreditation of Healthcare Organizations |
| **KFT** | Kidney function tests |
| **LFT** | Liver function tests |
| **MAP** | Mean arterial blood |
| **MRI** | Magnetic resonance imaging |
| **NIBP** | Non-invasive blood pressure |
| **NMDA** | N-methyl-D-aspartate |

| Abb. | Full term |
|---|---|
| **NMDA** | N-Methyl-D-Aspartate |
| **PCP** | Precursor phencyclidine |
| **PSA** | Procedural sedation and analgesia |
| **PT** | Prothrombin time |
| **PTT** | Partial thromboplastin time |
| **RBS** | Random blood sugar |
| **RR** | Respiratory rate |
| **RSS** | Ramsay sedation score |
| **SBP** | Systolic blood pressure |
| **$SpO_2$** | Peripheral oxygen saturation |

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# Ketofol vs Dexamedetomidine Effect on Conscious Sedation for Patients with Chronic Nonsurgical Low Back Pain

## Abstract

Low back pain is a common occurrence in the general population, affecting both sexes and all age groups, ethnic groups, and socioeconomic classes. Most patients recover quickly and without residual loss of function; however, recurrence is part of the natural history. Furthermore, chronic symptoms develop in 5% to 10% of patients. As a result, the cost to the individual and to society is enormous. The economic impact of chronic low back pain stems from prolonged loss of function, resulting in loss of work productivity, treatment costs, and disability payments. Intravenous (IV) sedation analgesia is often employed in patients with chronic spinal pain undergoing diagnostic spinal injection procedures. The drugs used for intravenous sedation analgesia produce varying degrees of sedation, amnesia, anxiolysis, muscle relaxation, and analgesia. They vary in nature according to their pharmacologic effects in altering the patient's level of consciousness, awareness, or response to a particular diagnostic stimulus. Ketofol is physically compatible and chemically stable and it can be stored at room temperature and under light. Ketamine is adding analgesia to propofol sedation, while vomiting and hallucination induced by ketamine are countered by propofol antiemetic and hypnotic properties. **Aim of the Work:** The aim of this study is to compare the effect of dexamedetomidine and ketofol on conscious sedation in patients undergoing non-surgical interventions for chronic low back pain regards the efficacy of sedation, hemodynamic stability, respiratory effects, speed of recovery, analgesic effects and incidence of complications. **Patients and Methods:** In this study, were 60 patients were randomly divided into 2 equal groups. **Results:** This study showed that the Dexmedetomidine group needed longer time to reach the targeted sedation score (RSS 3-4) compared to the Ketofol group and similarly a longer time is needed to recover from sedation and return to baseline conscious level. Regarding heart rates the dexmedetomidine group recorded lower readings compared to the ketofol group although there was no hemodynamic instability and the same was for mean blood pressure. **Conclusion:** Both drugs proved to be safe concerning respiration, $SPO_2$ and $CO_2$ values, however dexmedetomidine showed higher respiratory rates during the procedure. **Recommendation:** to carry a further study on using dexmedetomidine as a sedative in cardiac patients, thus assessing the degree of hemodynamic instability and its safety in those patients.

**Keywords:** Ketofol, Dexamedetomidine, Back Pain.

# Introduction

Low back pain is a common occurrence in the general population, affecting both sexes and all age groups, ethnic groups, and socioeconomic classes. Most patients recover quickly and without residual loss of function; however, recurrence is part of the natural history. Furthermore, chronic symptoms develop in 5% to 10% of patients. As a result, the cost to the individual and to society is enormous ***(Francis et al., 2006).***

The economic impact of chronic low back pain stems from prolonged loss of function, resulting in loss of work productivity, treatment costs, and disability payments ***(Allen et al., 2009).***

Patients medication is the most frequently used intervention for chronic low back pain. There is an increasing recognition that many patients are made to feel entitled to a "pain free" life ***(Andrew et al., 2011).***

Treatment of low back pain is challenging. A variety of therapeutic interventions is available, but no single modality appears to be superior, and evaluations vary depending on the cause of pain and on individual, social,

and occupational factors. Scientific evidence supports the use of some nonsurgical treatment alternatives in patients with acute and chronic low back pain ***(Francis et al., 2006).***

Intravenous (IV) sedation analgesia is often employed in patients with chronic spinal pain undergoing diagnostic spinal injection procedures. The drugs used for intravenous sedation analgesia produce varying degrees of sedation, amnesia, anxiolysis, muscle relaxation, and analgesia. They vary in nature according to their pharmacologic effects in altering the patient's level of consciousness, awareness, or response to a particular diagnostic stimulus ***(Howard et al., 2013).***

Recently dexmedetomidine had been successfully used in conscious (moderate) sedation as a good competitive to popular agent (midazolam). Also different concentrations of ketamine and propofol combinations (ketofol) were used for procedural sedation and analgesia ***(Hassan et al., 2015).***

Dexmedetomidine is a selective α-2 agonist with sedative and analgesic properties and its most important

advantage is that it does not cause respiratory depression ***(Yağan et al., 2015).***

Propofol is frequently used in sedation because of a rapid onset of action and a short recovery profile. It has hemodynamic and respiratory depressor effects depending on the dose. It has been reported that propofol can be used in combination with ketamine at a sub-hypnotic dose for providing an analgesic effect and the incidence of side effects can be decreased because of a reducible dose of propofol ***(Yağan et al., 2015).***

Ketamine is a N-Methyl-D-Aspartate (NMDA) receptor antagonist and has also been found to bind to opioid receptors. It is a phencyclidine derivatives and is classified as a dissociative sedation with fairly rapid onset and duration with little or no respiratory and cardiovascular depression. It causes amnesia and analgesia but its use as a single sedative agent has been limited because of its emergence reactions ***(Hassan et al., 2015).***

The combination of ketamine and propofol (ketofol) with low doses of each appeared with a better hemodynamic and respiratory stability ***(Hassan et al., 2015).***

Ketofol is physically compatible and chemically stable and it can be stored at room temperature and under light. Ketamine is adding analgesia to propofol sedation, while vomiting and hallucination induced by ketamine are countered by propofol antiemetic and hypnotic properties ***(Hassan et al., 2015).***

# Aim of the Work

The aim of this study is to compare the effect of dexamedetomidine and ketofol on conscious sedation in patients undergoing non-surgical interventions for chronic low back pain regards the efficacy of sedation, hemodynamic stability, respiratory effects, speed of recovery, analgesic effects and incidence of complications.

Chapter (1):

# Conscious Sedation

The American College of Emergency Physicians (ACEP) defines procedural sedation as "a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. Procedural sedation and analgesia (PSA) is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently ***(Miner et al., 2014).***

PSA was previously (and inappropriately) termed *conscious sedation*; indeed, the association of the two terms is contradictory because effective sedation reduces consciousness. Well tolerated PSA results in preservation of airway patency and spontaneous ventilation despite depressed levels of consciousness ***(Wakai et al., 2015).***

The number of noninvasive and minimally invasive procedures performed outside of the operating room has grown exponentially over the last several decades. Sedation, analgesia, or both may be needed for many of

these interventional or diagnostic procedures. Medications that elicit pharmacologic effects, such as anxiolysis, amnesia, or analgesia, provide patient comfort during various procedures. Understanding the efficacy and safe administration of these agents is essential to the practitioner performing interventional procedures ***(Aboumarzouk et al., 2011).***

PSA, even when adequately performed, may increase the risk of morbidity and mortality in addition to the diagnostic/therapeutic procedure itself. By recognising the intrinsic risks of PSA, the ***JCAHO*** *(Joint Commission on Accreditation of Healthcare Organizations)* in the USA mandates that PSA throughout any institution in the United States should be monitored and evaluated by the Department of Anaesthesia. Anaesthesia professionals are not required to be directly responsible for sedation services or their quality assurance, but rather to have an advisory and supportive role ***(Hinkelbein et al., 2018).***

## *Stages/levels of sedation*

There are several validated ways to define and assess levels of sedation. For example, below is a modified version of the five-level *Ramsay* scale, where level 5 is similar to, or synonymous with, general anaesthesia: