Clinical Assessment of Early Morning Blood Pressure in Patients with Hypertension

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Abstract
A significant population experiencing hypertension, blood pressure (BP) demonstrates a significant rise during the awakening hours, it is linked to heightened cardiovascular complications during this time of the day. Many medications used to manage high BP fail to effectively control BP in the early morning, especially when administered once daily in the morning. Key factors to consider when choosing an efficient antihypertensive medication include the agent's pharmacokinetics, formulation, and timing of dosing. Examples of antihypertensive drugs with proven efficacy in regulating early morning BP include medications with extended pharmacologic half-lives, like telmisartan (an angiotensin II receptor blocker), amlodipine (a calcium antagonist), and bisoprolol (a beta-blocker). Administering chronotherapeutic preparations at bedtime has also been shown to be effective in managing early morning BP. There is a correlation between elevated early morning BP and cardiovascular risk, future clinical studies should emphasize evaluating the performance of antihypertensive drugs during this critical period of heightened risk. (Prev Cardiol. 2007;10:210–214) © 2007 Le Jacq

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Introduction:
Blood pressure (BP) consists of a clear daily pattern, i.e.- a significant drop during sleep (known as the nocturnal dip) and a noticeable rise around the time of waking (referred to as the morning surge) (Figure 1). The incidence of acute
cardiovascular (CV) events, such as myocardial infarction, sudden cardiac death, and stroke, also follows a circadian rhythm, with the highest frequency observed in the morning hours (Figure 2) \(^1,2\). A substantial body of circumstantial evidence suggests a strong association between this heightened occurrence of CV events and the increase in BP levels during the early morning. For instance, the morning BP surge is positively linked to the extent of damage to target organs, including measures like carotid intima-media thickness\(^3\) and left ventricular hypertrophy\(^4\). Furthermore, the magnitude of the morning surge independently predicts cerebrovascular and cardiac events \(^5,6\). Although the impact of managing early morning BP on CV risk has not yet been thoroughly investigated in clinical trials, previously presented data indicate that focusing on better control of early morning BP holds promise for the treatment of hypertensive patients. In this review, we examine the factors governing the circadian variation in BP and assess the clinical significance of BP measurements taken at various times of the day using diverse measurement techniques. These approaches encompass measurements obtained in clinical or office settings, those collected during the early morning via 24-hour ambulatory BP monitoring (ABPM), and patient self-monitoring measurements. We also delve into the prognostic value of different BP measures and provide insights into the outcomes of recent trials that have incorporated 24-hour and early morning BP assessments. Finally, we evaluate antihypertensive agents that have demonstrated notable effectiveness in controlling early morning BP based on controlled clinical trials.

**Physiologic and Pathologic Circadian Variations in BP:**
The morning surge in blood pressure (BP) is influenced by various contributory factors. These factors possess alterations in autonomic and renin-angiotensin-aldosterone system activity, as discussed in previous studies\(^7\). Additionally, dietary sodium intake was also identified as a relevant factor\(^8\). In the early morning hours, several physiological changes occur that may potentially enhance cardiovascular (CV) risk. These changes include increased heart rate, increased vascular tone, elevated blood viscosity, and enhanced platelet aggregability\(^9\). Utilizing ambulatory blood pressure monitoring (ABPM) has proven instrumental in not only identifying individuals with excessive morning surges\(^10\) but also in enabling the assessment of the efficacy of antihypertensive agents that are effective in particular groups of hypertensive populations.

The typical nighttime reduction in blood pressure (BP), usually ranging between 10% and 20%, is primarily influenced by shifts in autonomic function \(^11\). Furthermore, the renin-angiotensin-aldosterone system, a crucial BP regulator, might also play a role, particularly in individuals sensitive to salt. The nocturnal BP pattern can be influenced by the intake of sodium and potassium in such cases \(^11\). Ambulatory blood pressure monitoring (ABPM) has enabled the identification of patients who exhibit deviations from the standard nocturnal BP pattern. These categories encompass Extreme Dippers: Individuals who manifest a significant ≥20% decline in nocturnal BP compared to daytime BP. Nondippers: These individuals experience a nocturnal BP decrease of less than 10% compared to their daytime BP. Inverted Dippers/Risers: This group includes patients in whom BP either remains stable or actually increases during the nighttime [Figure 1] \(^12\). These deviations in the nocturnal BP pattern have been linked to an elevated risk of cardiovascular disease and mortality\(^12,13\). Individuals classified as nondippers and risers typically do not exhibit a surge in BP upon awakening, but instead, they often experience sustained early morning hypertension (HTN). Conversely, extreme dippers frequently display an excessive morning surge\(^14\). It is crucial to acknowledge that physiologic and pathologic variations in BP are dynamic rather than static. Relying solely on a few BP measurements taken in a clinical setting provides isolated data points of a continuously evolving variable. Valuable clinical insights into BP behavior and its overall "burden" can be gleaned from monitoring systems that allow for the evaluation of nocturnal, early morning, and 24-hour BP patterns.

**Figure 1:** Normal circadian blood pressure (BP) rhythm is modified in some patients. The normal circadian BP rhythm features a nocturnal decrease in BP between 10% and 20% followed by a BP surge on awakening. Patients who exhibit this magnitude of nocturnal decrease in BP are known as dippers. Pathologic deviations from this normal pattern include extreme dipping (≥20% decline in nocturnal BP compared with daytime), nondipping (nocturnal BP decrease <10% of daytime BP), and inverted dipping/rising (nocturnal decrease/nocturnal increase)\(^12\). Patients who exhibit excess dipping typically show an excessive morning BP surge\(^14\). Adapted with permission from Giles\(^7\).
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monitoring (ABPM) has proven instrumental in not only influenced by shifts in autonomic activity usually ranging between 10% and 20%, is primarily the typical nighttime reduction in blood pressure (BP), antihypertensive agents that are effective in particular groups cardiovascular (CV) events, such as myocardial infarction, salt. The nocturnal BP pattern can be influenced by the variation in BP and assess the clinical significance of BP surge independently predicts cerebrovascular and cardiac guidelines established through a comprehensive review of blood pressure (ABP) measurements, consensus variations encompass phenomena like many of which are linked to an elevated risk of adverse to identify several pathological variations in this pattern, daytime (while individuals are awake), nighttime (during the sleep cycle), and across a complete 24-hour cycle. According to consensus criteria endorsed by an expert group affiliated with the American Heart Association, hypertension is diagnosed when ABPM readings equal or surpass the threshold of ≥135/85 mm Hg during daytime hours and ≥120/70 mm Hg during nighttime hours, or ≥130/80 mm Hg when considering the entire 24-hour period.

**Measurement of BP:**

Blood pressure (BP) assessment can occur within clinical settings, where medical professionals, including physicians or nurses, utilize various methods such as Ambulatory Blood Pressure Monitoring (ABPM), or in the comfort of one’s home through self-monitoring or home-based monitoring. Despite the well-established clinical relevance of BP measurements conducted in a clinical environment, there are inherent limitations associated with this approach. These limitations encompass potential equipment calibration issues, deviations from recommended measurement protocols by healthcare practitioners, and the well-known phenomenon known as the "white coat effect." Notably, clinic-based BP measurements do not provide a comprehensive view of BP values 12 to 24 hours after medication dosing and are unable to capture BP fluctuations during sleep or the post-awakening surge. In the clinical context, an upper limit of normalcy for BP measurements is typically defined as 140/90 mm Hg for most patients. However, individuals with hypertension (HTN) alongside diabetes mellitus or kidney disease are often assigned a lower BP target of <130/80 mm Hg. In the context of ambulatory blood pressure (ABP) measurements, consensus guidelines established through a comprehensive review of existing literature have defined the reference values. These ABP assessments involve calculating averages during the

**Figure 2:** Occurrence of cardiovascular events peaks during the morning hours. Sudden cardiac death and nonfatal myocardial infarction both occur in a marked circadian rhythm, with a trough between midnight and 4 a.m. and a peak between 6 a.m. and noon. Reproduced with permission from Muller et al.1

**Figure 3:** Bedtime administration of extended-release diltiazem (240–540 mg) is significantly more effective than bedtime administration of ramipril (5–20 mg) in reducing systolic and diastolic blood pressure (BP) in the first 4 hours after awakening (P≤.002). Adapted with permission from White et al.27

**Figure 4:** Reductions in 24-hour systolic and diastolic blood pressure (BP) after treatment with telmisartan alone or in combination with hydrochlorothiazide from the MICCAT-2 trial. In a 6- to 10-week community-based trial, a cohort of treated (n=675) and untreated (n=940) hypertensive patients were switched to started with telmisartan-based antihypertensive therapy (telmisartan, 40–80 mg ± hydrochlorothiazide, 12.5 mg). Patient BP was monitored in the physician’s office and using ambulatory BP monitoring. Telmisartan-based therapy was associated with significant reductions in systolic and diastolic BP in previously treated and previously untreated patients, in men and women, and in patients younger than 65 years and those aged 65 years or older (P<.0001 for all values). Adapted with permission from White et al.33
It's noteworthy that ABPM measurements typically yield lower values compared to BP measurements taken in clinical settings, resulting in a corresponding reduction in the threshold for defining normal daytime BP (<135/85 mm Hg versus <140/90 mm Hg). Furthermore, BP readings are generally lower when measured by patients at home compared to in-office measurements. A recent examination of home-based, office-based, and ABPM readings proposed that individuals with home BP measurements below <125/76 mm Hg could be categorized as normotensive, those with home BP values ≥135/85 mm Hg should be classified as hypertensive, while individuals with intermediate home BP readings should undergo further evaluation, preferably utilizing ABPM. Self-monitoring of BP presents several advantages over traditional clinic-based BP measurement, particularly when employing modern, validated electronic devices. A recent meta-analysis of 18 rigorously conducted randomized controlled trials revealed that self-monitoring of BP was linked to significantly improved BP control compared to the customary office-based measurement approach. Self-monitoring at home also provides patients with a heightened sense of control and engagement in their health. While it may not facilitate the assessment of the nighttime BP pattern, diligent self-monitoring can serve as a valuable tool in identifying early morning hypertension.

Prognostic Value of Different BP Measurements:
Monitoring blood pressure at home has been found in various studies to be more accurate in predicting cardiovascular events, cardiovascular-related deaths, and damage to target organs when compared to clinic-based blood pressure measurements. However, many of these studies were conducted on general populations, making it challenging to establish normal self-monitoring values based solely on their findings.

In a particular study involving 393 untreated elderly patients, with an average age of 70, suffering from isolated systolic hypertension and enrolled in the Systolic Hypertension in Europe (Syst-Eur) trial, it was discovered that ambulatory systolic blood pressure emerged as a significant predictor of cardiovascular risk, while systolic blood pressure measured in a clinical setting did not exhibit the same predictive power. Intriguingly, nighttime systolic blood pressure proved to be an even more accurate predictor of risk than daytime measurements. Similar results were reported by Clement and colleagues in a 5-year prospective cohort study, which involved 1963 middle-aged patients receiving antihypertensive treatment (with a mean baseline age of 56–57 years). In this prospective cohort study, baseline ambulatory blood pressure monitoring values remained significant independent predictors of cardiovascular events, even after accounting for major cardiovascular risk factors and clinic-based blood pressure readings.

Furthermore, through multivariate analyses that considered serum cholesterol levels, smoking habits, and the presence of diabetes, Björklund and associates demonstrated that ambulatory daytime systolic blood pressure and the presence of isolated ambulatory hypertension (defined as having a normal office-measured blood pressure but elevated ambulatory blood pressure, also known as masked or hidden hypertension) were both independent predictors of cardiovascular disease, while clinic-based systolic blood pressure measurements did not provide the same level of prediction.

Lastly, when comparing the efficacy of ambulatory blood pressure monitoring and clinic-based measurements in managing hypertensive patients, it was observed that, although both clinic and ambulatory readings were associated with similar levels of antihypertensive control and inhibition of left ventricular enlargement, patients monitored using ambulatory blood pressure monitoring required less intensive drug treatment.

Efficacy of Antihypertensive Agents in Controlling 24-Hour and Early Morning BP:
Achieving effective control of early morning and 24-hour mean ambulatory blood pressure [ABP] has become a highly sought-after feature of antihypertensive treatments. The extent to which antihypertensive agents can regulate blood pressure during the night and early morning hours depends on various factors, including pharmacokinetics, formulation, and timing of administration.

For instance, graded-release diltiazem is a chronotherapeutic formulation designed to counteract the circadian rhythm of blood pressure. When administered in the evening, it proves more effective than morning administration in lowering blood pressure between 6 AM and noon. Furthermore, in a double-blind, titration-to-effect trial, White and colleagues demonstrated that bedtime administration of graded-release diltiazem was notably more effective at reducing early morning blood pressure than bedtime administration of ramipril (Figure 3). Similarly, administering a controlled-onset extended-release verapamil formulation at bedtime proved superior in lowering early morning blood pressure compared to the morning administration of enalapril or losartan.

Utilizing agents with longer half-lives has also shown promise in enhancing early morning blood pressure control. For example, a single 10-mg dose of the beta-blocker bisoprolol, taken in the morning, effectively lowered blood pressure throughout the entire 24-hour period. After four weeks of treatment in a group of 25 patients with essential hypertension, bisoprolol reduced the mean morning blood pressure from 145/97 mm Hg to 133/88 mm Hg. Similarly, the calcium channel blocker amlodipine reduced morning systolic blood pressure and mitigated the magnitude of the morning systolic blood
pressure surge. In a study involving 38 hypertensive patients who received amlodipine (2.5–10 mg) immediately after breakfast for 8 to 16 weeks, the mean morning systolic blood pressure decreased from 156 mm Hg to 142 mm Hg, and the morning surge diminished by 6.1 mm Hg.30

Recent insights into the activation of the renin-angiotensin-aldosterone system during sleep and in the early morning have prompted the investigation of angiotensin II blockade as a strategy for controlling early morning hypertension. Telmisartan, an angiotensin receptor blocker with an extended half-life, has proven effective in reducing early morning blood pressure.10,31 In two large-scale trials comparing telmisartan with valsartan, telmisartan at doses of 40–80 mg outperformed valsartan at doses of 80–160 mg in reducing blood pressure during the last 6 hours of the inter dosing interval, aligning with the early morning period.31,32

Moreover, the effectiveness of this therapeutic approach to ABP was evaluated in a significant, prospective, open-label trial conducted in a primary care setting (the Micardis Community Ambulatory Monitoring Trial [MICCAT-2]). In this trial, telmisartan [with or without hydrochlorothiazide] significantly reduced 24-hour, daytime, nighttime, and early morning [post awakening] mean blood pressure in both previously treated and untreated hypertensive patients.10,33 Specifically, post awakening blood pressure decrease by an average of 17.2/10.1 mm Hg in patients with an excessive morning blood pressure surge, surpassing the effect observed in the overall population (reduction of 11.5/7.0 mm Hg).10

The Prospective Randomized Investigation of the Safety and Efficacy of Micardis vs. Ramipril Using ABPM (PRISMA) studies also examined the effectiveness of telmisartan 80 mg/day compared to ramipril 10 mg/day in controlling the morning blood pressure surge in patients with mild to moderate hypertension. Pooled data from PRISMA I and II demonstrated that telmisartan reduced the overall mean morning systolic blood pressure surge, whereas patients taking ramipril experienced an increase in the morning blood pressure surge.34 Notably, the reduction in morning systolic blood pressure surge was most pronounced in patients with the highest baseline morning systolic blood pressure surge.34 Telmisartan also significantly reduced the magnitude of the systolic morning blood pressure surge in diabetics compared to ramipril, although no significant difference was observed in nondippers.34

Conclusions:
In individuals with good health, blood pressure exhibits a highly consistent circadian rhythm. Analyzing and understanding this pattern has been significantly enhanced by ambulatory blood pressure monitoring (ABPM), a technique proven to be more effective than clinic-based blood pressure measurements in predicting adverse events. ABPM has also enabled healthcare professionals to identify several pathological variations in this pattern, many of which are linked to an elevated risk of adverse events. These variations encompass phenomena like nocturnal nondipping and excessive morning blood pressure surges.

The early morning surge in blood pressure is of particular concern because it aligns with the peak occurrence time of cardiovascular events. Consequently, physicians and pharmaceutical researchers have directed their attention toward developing antihypertensive agents specifically tailored to address this critical morning period. Notable among these are chronotherapeutic formulations of diltiazem and verapamil, as well as medications with extended half-lives, typically spanning 20 to 30 hours. Examples include the angiotensin II receptor blocker telmisartan and the beta-blocker bisoprolol, both of which exhibit significant efficacy during the early morning hypertensive phase.

Given the well-established association between early morning blood pressure and cardiovascular risk, it is imperative that future clinical trials place a deliberate focus on evaluating the effectiveness of antihypertensive drugs during this crucial time window.

Conflict of Interest: None.

References:
Introduction:

Identification of individuals with excessive morning surges in blood pressure (BP) has proven instrumental in not only understanding their circadian rhythm of BP but also in assessing their cardiovascular risk. The typical nighttime reduction in BP, which is known as the nocturnal BP decline, is a well-recognized phenomenon. However, in some individuals, this decline does not occur, leading to reduced nighttime systolic blood pressure (BP) that is often accompanied by a marked morning surge.

Morning BP surge is a term used to describe an exaggerated increase in systolic BP upon awakening, but instead, they often experience a decline in BP during the early morning hours. This surge independently predicts cerebrovascular and cardiac events and has been linked to an elevated risk of nonfatal myocardial infarction. Furthermore, the morning surge has been associated with the presence of isolated ambulatory blood pressure monitoring (ABPM) values.

It is crucial to acknowledge that physiologic and pharmacologic factors can influence BP behavior. Relying solely on a few BP measurements taken in a clinical setting can lead to misinterpretation of the true circadian BP pattern. Clinical insights into BP behavior have been significantly enhanced through the use of ABPM, which allows for the assessment of BP throughout the day and night in real-world conditions.

Valuable clinical insights into BP behavior, encompass potential equipment calibration issues, and BP variability. The normal circadian BP pattern has been linked to an elevated risk of cardiovascular disease, with the morning surge being a particularly strong predictor of cardiovascular events. The American Heart Association and the European Society of Hypertension have defined the reference values for BP in different age groups.

Excessive morning surges are identified by an increase in systolic BP of 10 mm Hg or more compared to the morning administration of enalapril or losartan. In individuals with good health, blood pressure exhibits a circadian rhythm of BP. When administered in the morning, diltiazem and verapamil, as well as medications with longer half-lives, have shown to effectively reduce blood pressure during the night and early morning hours. Medications such as losartan and hydrochlorothiazide significantly reduced 24-hour, nighttime systolic blood pressure, whiletelmisartan and valsartan at doses of 80–160 mg in reducing blood pressure during the night and early morning hours.

Utilizing agents with longer half-lives has also shown to be effective in reducing morning surges. For instance, bedtime administration of graded-release diltiazem significantly reduced systolic and diastolic blood pressure in patients with an excessive morning surge.

In a study involving 38 hypertensive patients, the mean blood pressure in both previously treated and untreated hypertensive patients was reduced by 17.2/10.1 mm Hg. In a cohort of treated and untreated patients, the mean blood pressure in both groups was reduced by 11.5/7.0 mm Hg. In a randomized controlled trial, the mean blood pressure in both previously treated and untreated patients was reduced by 11.5/7.0 mm Hg. In another study, telmisartan with or without hydrochlorothiazide significantly reduced 24-hour, nighttime systolic blood pressure prove to be an even greater predictor of overall population (reduction of 11.5/7.0 mm Hg). Both hypertensive patients had ambulatory blood pressure monitoring values remained associated with similar levels of antihypertensive control provide the same level of prediction for mortality than does screening blood pressure measurement: a population-based observation in Ohasama, Japan. The J Hypertens. 1998;16:971-975. and cardiovascular target organ damage. A cross-sectional study. Circulation. 2003;107:1401-1406. and cardiovascular target organ damage. A cross-sectional study. Circulation. 1987;75:131-138.

Discrepancies in BP values between self-monitoring measurements and clinic measurements have been observed. Furthermore, the self-monitoring of BP presents several challenges. One of which is the potential for equipment calibration issues, making it challenging to establish normal self-monitoring values.

Ambulatory Blood Pressure Monitoring (ABPM), or in other words, a 24-hour BP trace, has been utilized as a gold standard in monitoring BP in the general population. However, these studies were conducted on general populations, and the reference values for ABPM have been modified in some patients. The normal circadian BP pattern have been linked to an elevated risk of cardiovascular disease in elderly hypertensives: a prospective study. Circulation. 2003;107:1401-1406. and cardiovascular target organ damage. A cross-sectional study. Circulation. 1987;75:131-138.

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